Exhibit 1

Expert Report of Andrew Kolodny, M.D.

Dated: August 3, 2020

I. INTRODUCTION AND SUMMARY OF OPINIONS

I have been retained by Plaintiffs Cabell County and the City of Huntington ("Plaintiffs," "the Cabell-Huntington Community") to opine on whether the conduct of McKesson Corporation ("McKesson"), AmerisourceBergen Drug Corporation ("AmerisourceBergen") and Cardinal Health, Inc. ("Cardinal") (collectively "Defendants"), either alone or together, diminished the Cabell-Huntington Community's health and safety and whether Defendants' conduct was a substantial factor in causing a public nuisance in the Cabell-Huntington Communities.

Specifically, I was asked to address whether, in my professional opinion, the Defendants' conduct was a substantial factor in causing an unreasonable interference with rights common to the general public, including the public's rights to health and safety, and whether Defendants' conduct produced a permanent or long lasting effect that they knew or should have known would have significant impacts on any of these public rights.

Finally, I was asked to opine on evidence-based solutions to the current opioid crisis in Cabell County and the City of Huntington, West Virginia.

In undertaking this assignment, I have been asked to apply my years of experience in public health, public policy, addiction medicine; and years of study regarding the opioid epidemic and its root causes to evaluate the circumstances and potential involvement of the Defendants in the facts and circumstances that led to the opioid crisis that the Cabell-Huntington Community is now facing.

In answering these questions, I was provided the following legal definitions.

> A ***public nuisance*** is an act or condition that unlawfully operates to hurt or inconvenience an indefinite number of persons. In other words, a public nuisance affects the general public. The definition of a public nuisance is consistent with the RESTATEMENT (SECOND) OF TORTS § 821B(1), which defines a public nuisance as "an unreasonable interference with a right common to the general public."' Circumstances that may sustain a holding that an interference with a public right is unreasonable include the following:
>
> > (a) Whether the conduct involves a significant interference with the public health, the public safety, the public peace, the public comfort or the public convenience, or
> > (b) whether the conduct is proscribed by a statute, ordinance or administrative regulation, or
> > (c) whether the conduct is of a continuing nature or has produced a permanent or long-lasting effect, and, as the actor knows or has reason to know, has a significant effect upon the public right.
>
> The above three factors for determining whether an interference with a public right is unreasonable are listed in the disjunctive; thus, a finding that a Defendant Distributor's conduct meets any one of them may warrant a holding of unreasonableness.

My opinions, offered in greater detail in Section VI below, can be summarized as follows:

1. There has been a sharp increase in the prevalence of opioid addiction in the United States, in West Virginia and in the Cabell-Huntington Community. The increased prevalence of opioid addiction has resulted in an array of health and social problems commonly referred to as "the Opioid Epidemic." These problems include but are not limited to overdose deaths, neonatal opioid withdrawal, impact on family services, injection-related infectious diseases, increased use of heroin and other illicit drugs, and an impact on the workforce.

2. The increased prevalence of opioid addiction was caused by overexposing the United States population, especially people in the State of West Virginia and the Cabell-Huntington Community, to prescription opioids, and is still primarily driven by prescription opioids.

3. Overexposure of the population to prescription opioids was a consequence of an enormous oversupply of prescription opioids by the pharmaceutical industry, including the Defendants.

4. The Defendants' conduct in flooding the United States, West Virginia and the Huntington-Cabell Community with prescription opioids was not only reckless and below any reasonable standard, it was also a substantial factor in causing the Opioid Epidemic in the Huntington-Cabell Community.

5. Specifically, the following conduct by each of the Defendants was a substantial factor in causing the flood of prescription opioids into the United States, West Virginia and the Huntington-Cabell Community, fell below any reasonable standard of care, and these factors combined synergistically to produce a severely negative impact on the Cabell-Huntington Community public health and safety:

    a. Defendants worked to dramatically expand and then maintain the market, the demand and, therefore, the supply of prescription opioids through participating in a massive marketing and misinformation campaign about opioids.

    b. Defendants flooded an already saturated market with such a large amount of highly addictive narcotics that abuse, addiction, misuse and diversion of pills was not only foreseeable, but inevitable.

    c. Defendants continued to dramatically increase the supply of prescription opioids despite mounting evidence that the oversupply was resulting in catastrophic public health consequences, including rising opioid-related morbidity and mortality.

    d. Defendants continued to conduct business with companies that were cited for illegal or improper conduct with respect to prescription opioid promotion and/or supply.

e. Defendants were repeatedly and blatantly cited for breaking the law designed to control oversupply and prevent diversion.

f. Defendants misrepresented the quality of their anti-diversion programs to keep regulatory and public scrutiny at bay and continue selling unchecked.

g. In blatant disregard for public health and safety, including that in the Huntington-Cabell Community, Defendants have refused to take responsibility for the epidemic, even today, and have tried to shift blame to others, including people who became addicted to opioids because of their wrongdoing.

6. The conduct of the Defendants, working individually and together, was a substantial factor in causing the Opioid Epidemic. Working closely with each other and their business partners in the supply chain (namely the opioid manufacturers and chain pharmacies) without reasonable care, their reckless behavior and blatant violations of the laws and regulations were a substantial cause of the Opioid Epidemic.

7. The harm to public health, safety and welfare in Plaintiffs' communities caused by Defendants' conduct was not only unreasonable, it was foreseeable and preventable.

8. Even with the proper interventions, the Opioid Epidemic will impact the Huntington-Cabell Community for several decades.

9. There are evidence-based solutions that can be implemented, albeit over time and with the right resources, that can control the epidemic in the Huntington-Cabell Community and should be implemented.

My opinions and the basis for those opinions are further summarized in Sections VI and are based on my knowledge, training and experience in the fields of addiction medicine and public health; review of the relevant medical literature, and a review of documents and materials set forth in Schedule 3 and 4 to this Report. I offer the opinions contained herein to a reasonable degree of medical certainty in the fields of public health and addiction medicine.

I reserve the right to amend or supplement the facts and opinions upon which I am expected to testify as additional information is made available.

II. BACKGROUND AND QUALIFICATIONS

I am a medical doctor, Board Certified in Addiction Medicine, Psychiatry & Neurology. My clinical specialty is the treatment of opioid use disorder. I have been working on the Opioid Epidemic for the past 17 years, initially as a public health official for New York City, then as a clinician, researcher and advocate.

I currently serve as the Medical Director of the Opioid Policy Research Collaborative at the Heller School for Social Policy and Management at Brandeis University in New York. The Opioid Policy Research Collaborative helps form public health policy related to the Opioid

Epidemic, including educating stakeholders regarding the causes of the Opioid Epidemic and advising policymakers, health officials, legislators, government officials and other stakeholders regarding evidence-based solutions to the opioid crisis. Additionally, I teach a course about the Opioid Epidemic to master's in public health students at Columbia University. In the course, students learn about the origin of the crisis, the epidemiology of opioid use disorder and strategies for controlling the epidemic. I am also the co-founder and executive director of Physicians for Responsible Opioid Prescribing, an organization with a mission to reduce morbidity and mortality caused by overprescribing of opioid analgesics.

I received my medical degree from Temple University School of Medicine in 1999, followed by an internship at Mount Sinai School of Medicine, and a residency in Psychiatry at Mount Sinai School of Medicine. During that time, I began to focus on public health issues, completing a fellowship in health policy in the United States Senate and also a fellowship in Public Psychiatry at Columbia University School of Medicine. In 2003, during my fellowship at Columbia, I went to work for the New York City Department of Health and Mental Hygiene, where I later became the Medical Director in the Office of the Executive Deputy Commissioner.

As a medical director in the New York City Department of Health and Mental Hygiene, I led one of the nation's first public health efforts to address the Opioid Epidemic, including an initiative to reduce opioid overdose deaths by distributing naloxone through syringe exchange programs and an initiative to expand access to treatment of opioid addiction with buprenorphine. In 2004, while still working for New York City, I began a clinical practice specializing in the treatment of opioid use disorder.

Having the opportunity to work in public health, a field focused on population-based disease prevention, while maintaining a clinical practice allowed me to recognize that a new epidemic of opioid addiction had emerged. Past drug addiction epidemics had historically impacted New York City's poorest neighborhoods but through my work, I came to recognize that the new epidemic was impacting middle class communities. The opioid-addicted patients streaming into my office were from comfortable neighborhoods. Learning that my patients had developed opioid addiction from use of prescription opioids made me begin to question medical education downplaying the risk of addiction. And because my public health work gave me ready access to national surveillance data, I was also able to see that in other parts of the country, especially the Appalachian region, the rate of opioid-related overdose deaths and hospital visits were even higher than in New York City and increasing at an alarming rate.

In 2006, I became the Vice Chair (and later the Chair in 2008) of the Department of Psychiatry at Maimonides Medical Center, one of the largest teaching hospitals in the country, located in Brooklyn, New York. While in this position I supervised the psychiatric treatment in the medical center's emergency department, outpatient programs, and inpatient units, and I witnessed first-hand a rising number of patients suffering from opioid addiction.
Shortly after arriving at Maimonides Medical Center, I came across a journal article written by the CDC, which helped me understand the sharp rise in opioid-related morbidity and mortality.[1]

[1] Paulozzi LJ, Budnitz DS, Xi Y. (2006) Increasing deaths from opioid analgesics in the United States. *Pharmacoepidemiol Drug Saf.*, 15(9), 618-627. doi: 10.1002/pds.1276

The CDC showed that opioid overdose deaths had increased in parallel with sales for opioid analgesics and explained that the Opioid Epidemic had been caused by "more aggressive pain management." For the first time, a primary cause of the crisis was made clear, however, in the same medical journal a university-based opioid industry front group published a commentary attacking the CDC paper, attempting to cast doubt on its findings.

Recognizing that the opioid industry was interfering with efforts to understand and respond to a crisis it sparked my research interest in the industry-funded campaign to increase prescribing and in the relationship between the opioid industry and pain organizations. Is also precipitated my interest in advocacy for more cautious prescribing.

In 2010, several of my colleagues and I founded Physicians for Responsible Opioid Prescribing (PROP). I currently serve as the Executive Director of that organization. A significant part of the group's effort has focused on educating the medical community. Our educational materials explicitly correct past misinformation that can result in improper prescribing. PROP's leadership has conducted research, published papers, petitioned federal agencies and communicated with state and federal policymakers about the role of improper and deceptive marketing of opioids, about the devastation the oversupply of opioids has caused and the potential solutions for repairing the damage that was done to communities around the United States.

In 2013, I left Maimonides to become the Chief Medical Officer of Phoenix House, a national, nonprofit addiction treatment provider, offering affordable evidence-based care to teens, adults, and families, including unique programming for mothers with young children and veterans. In this capacity, I helped Phoenix House adapt its clinical programming nationwide to meet the needs of patients with opioid use disorder.

In 2012, because of my work on the opioid industry's relationship with front groups and key opinion leaders, I was consulted by the United States Senate Finance Committee with respect to its investigation of opioid manufacturers and pain organizations. I have also been asked to provide my expertise on the causes of, and potential solutions to, the Opioid Epidemic for numerous stakeholders including the World Health Organization, the National Governors Association, the National Association of State Attorneys General, the National Judicial Opioid Task Force, the National Academy of Sciences, and Bi-partisan Members of Congress. I have been invited to testify before committees of the United States Senate and House of Representatives, including the Senate International Drug Caucus, the Senate Committee on Homeland Security and the House Energy and Commerce Committee. Often in the course of this work I review documents of the kind I have looked at here to offer opinions regarding the causes of the Opioid Epidemic, including: internal documents of the pharmaceutical companies; documents evidencing financial backing of pharmaceutical companies of organizations, publications or associations; governmental studies and task force reports; governmental investigative documents; public statements made by pharmaceutical companies, government entities and various stakeholders; public new stories and investigative reporting and sworn testimony. It is often important, in the course of this work to determine what companies knew, what they should have known and what they did with the information they had.

My work tackling the Opioid Epidemic as a health official, clinician, researcher and advocate has given me the knowledge and experience to discuss facts and offer opinions on the root causes of the Opioid Epidemic and the actions that must be taken to bring this urgent public health crisis under control.

My background and qualifications for offering expert opinions are further summarized in my Curriculum Vitae, a copy of which is attached hereto as **Schedule 1**.

III. COMPENSATION

I am being compensated for my work in this case at the following rate: $780 per hour for testimony and preparation.

IV. PRIOR TESTIMONY AND PUBLICATIONS

A list of the testimony I have in the last four years in legal matters is attached hereto as **Schedule 2**.

A list of the publications I have authored in the last ten years is included in my CV, attached hereto as **Schedule 1.**

V. MATERIALS CONSIDERED

In addition to my knowledge, training and experience and the documents and publications cited throughout this Report, attached as **Schedule 3** is a list of the materials I considered in forming my opinions in this Report. I will supplement this list as additional materials become available.

VI. DETAILED OPINIONS AND BASIS:

1. The Basics of Opioid Addiction and Physiological Dependence

Opioids are drugs that stimulate the brain's opiate receptors. Some are made from opium and some are completely synthetic. In the U.S., the most commonly prescribed opioids are hydrocodone and oxycodone, which are classified as semi-synthetic because they are synthesized from opium. Heroin is also a semi-synthetic opioid. The effects of hydrocodone and oxycodone on the brain are nearly indistinguishable from the effects produced by heroin. In fact, in a study performed at Columbia University, experienced heroin users preferred the effects of oxycodone to heroin.[2]

Opioids interact with the mu or kappa receptors in the brain, spinal cord, and other areas of the body, especially those involved in feelings of pleasure and pain. Opioids can produce an analgesic effect by acting on receptors located on neuronal cell membranes. The presynaptic action of opioids is considered to be their major effect in the nervous system. In addition to

[2] Comer SD, et al. (2008). Abuse liability of prescription opioids compared to heroin in morphine-maintained heroin abusers. *Neuropsychopharmacology*, 33(5), 1179-1191. https://doi.org/10.1038/sj.npp.1301479

analgesic effects, however, opioids also have well-known and serious dangers associated with them, including a risk of respiratory depression, addiction, dependence, overdose and death.

Addiction is defined as continued use of a drug despite negative consequences.[3] Repeated exposure to highly addictive drugs can result in dysfunction in neurological pathways that impact behavior. This is reflected in an individual pathologically pursuing reward and/or avoidance of dysphoria by continued use of a substance. Addiction is typically characterized by inability to abstain, difficulty controlling use, craving, and diminished recognition of problems caused by drug use. Addiction is similar to other chronic diseases in that individuals are often prone to cycles of relapse and remission. Without treatment, addiction can be progressive and can even result in premature death.

Addiction to opioids is also referred to as Opioid Use Disorder (OUD). The American Psychiatric Association (APA) has put forth a series of clinical criteria for use in diagnosing Opioid Use Disorder as follows:[4]

> **Opioid Use Disorder:** OUD is defined as two or more of the following within a 12-month period:
>
> 1. Using larger amounts of opioids or over a longer period than was intended
> 2. Persistent desire to cut down or unsuccessful efforts to control use
> 3. Great deal of time spent obtaining, using, or recovering from use
> 4. Craving, or a strong desire or urge to use substance
> 5. Failure to fulfill major role obligations at work, school, or home due to recurrent opioid use
> 6. Continued use despite recurrent or persistent social or interpersonal problems caused or exacerbated by opioid use
> 7. Giving up or reducing social, occupational, or recreational activities due to opioid use
> 8. Recurrent opioid use in physically hazardous situations
> 9. Continued opioid use despite physical or psychological problems caused or exacerbated by its use
> 10. Tolerance (marked increase in amount; marked decrease in effect)
> 11. Withdrawal syndrome as manifested by cessation of opioids or use of opioids (or a closely related substance) to relieve or avoid withdrawal symptoms.

Opioids are highly addictive because they induce positive effects, such as euphoria and pain relief (positive reinforcement) and cessation of chronic use produces dysphoria (negative reinforcement). Chronic exposure to opioids results in structural and functional changes in

[3] Angres DH, Bettinardi-Angres K. (2008). The disease of addiction: origins, treatment, and recovery. *Dis. Mon.*, 54(10), 696–721 doi: 10.1016/j.disamonth.2008.07.002

[4] American Psychiatric Association., American Psychiatric Association. DSM-5 Task Force. *Diagnostic and statistical manual of mental disorders: DSM-5*. 5th ed. Washington, D.C.: American Psychiatric Association; 2013.

regions of the brain that mediate affect, impulse, reward, and motivation.[5] The disease of opioid addiction arises from repeated exposure to opioids and can occur in individuals using opioids to relieve pain and in nonmedical users. Studies have found that many patients on long-term opioids for chronic pain meet criteria for DSM-V opioid use disorder and DSM-IV opioid dependence.[6]

Opioids affect the central part of the brain that regulates breathing and when enough opioids are taken, they can slow down breathing to the point of fatal respiratory depression. Opioid induced respiratory depression can eventually cause cardiac arrest. Respiratory depression caused by opioids has become the leading cause of unintentional injury death in the United States.[7]

Not only can opioid use cause addiction, overdose and death, but for all opioid users physiological dependence sets in within a few days of regular use.[8] The opioid withdrawal symptoms experienced when a physiologically dependent patient attempts to cease use can be severe, especially in patients who have used opioids for a prolonged period of time or were taking high doses. In the first few days after opioids are discontinued, withdrawal effects include flu-like symptoms, nausea, vomiting, diarrhea, pain hypersensitivity, insomnia and severe anxiety, akin to a panic attack and described in the medical literature as "a sense of impending doom."[9] Patients who have experienced opioid withdrawal often describe the experience as "feeling like I was going to die." Individuals who are physiologically dependent on opioids will

[5] Upadhyay J, et al. (2010). Alterations in brain structure and functional connectivity in prescription opioid-dependent patients. *Brain*, 133(Pt7), 2098–114 doi: 10.1093/brain/awq138; Younger JW, et al. (2011). Prescription opioid analgesics rapidly change the human brain. *Pain*, 152(8), 1803–10. doi: 10.1016/j.pain.2011.03.0280

[6] Boscarino JA, Hoffman SN, Han JJ. (2015). Opioid-use disorder among patients on long-term opioid therapy: impact of final DSM-5 diagnostic criteria on prevalence and correlates. *Subst Abuse Rehabil*., 6, 83-91. doi: 10.2147/SAR.S85667; Boscarino JA, Rukstalis MR, Hoffman SN, et al. (2011). Prevalence of prescription opioid-use disorder among chronic pain patients: comparison of the DSM-5 vs. DSM-4 diagnostic criteria. *J Addict Dis*., 30(3), 185-194. doi: 10.1080/10550887.2011.581961

[7] Nat'l Acads. of Science, Eng'g and Medicine, *Pain Mgmt. and the Opioid Epidemic*, National Academies Press (2017) at 17 (citing Rose Rudd, et al, (2016). Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015, MMWR *Morb Mortal Wkly Rep,* 65 (50-51), 1445-52. DOI: http://dx.doi.org/10.15585/mmwr.mm655051e1

[8] Kosten, T. et al., (2002). The Neurobiology of Opioid Dependence: Implications for Treatment, *1 Science Practical Perspective*, 1, 13–20 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2851054; Bailey, C. & Connor, M. *Opioids: Cellular Mechanisms of Tolerance and Physical Dependence*, 5 Current Opinion in Pharmacology 1, at 60, https://www.ncbi.nlm.nih.gov/pubmed/15661627; Shah, A. et al., *Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use- Unites States, 2006-2015*, Morbidity and Mortality Weekly Report (Mar. 17, 2017), *available at* https://www.cdc.gov/mmwr/volumes/66/wr/mm6610a1.htm

[9] San, L. et al., (1992) Assessment and Management of Opioid Withdrawal Symptoms in Buprenorphine-Dependent Subjects, *British J. of Addiction*, 87(1), 55-62; Kosten, *supra* at note 31.

often engage in desperate and sometimes illegal activities to maintain their opioid supply and avoid withdrawal.

Individuals who take high doses of opioids for an extended period of time can experience opioid withdrawal symptoms for several months after use is discontinued.[10] These prolonged symptoms include metabolic abnormalities, insomnia, fatigue and depression and cravings to use opioids.

Opioids are essential medicines for palliative care. They can also be helpful when used for a few days after major surgery or a serious accident. Unfortunately, the bulk of opioid consumption in the U.S. is for common, chronic conditions, like back pain, where opioids may be more likely to harm patients than help them. There is not, and has never been, strong evidence to support the effectiveness of using opioids long-term to treat chronic pain, or for conditions beyond palliative care and acute pain.[11] In developing the CDC Guideline for Opioid Prescribing for Chronic Pain, CDC conducted a systematic review of the scientific evidence to identify the effectiveness, benefits, and harms of long-term opioid therapy for chronic pain. CDC found only one study addressing effectiveness of high dose opioids for outcomes related to pain control, function, and quality of life.[12] This randomized trial found no difference in pain or function between a more liberal opioid dose escalation strategy and maintenance of current dosage. At the same time, CDC noted serious harms related to high dose opioid therapy.[13]

Despite the opioid industry's aggressive promotion of long-term opioids for chronic pain, evidence suggests that the risks of daily opioid use outweigh potential benefits. When taken every day, patients quickly become tolerant to the pain-relieving effects, which means that the dose will need to be increased to experience the analgesic effect. As doses get higher the risks for serious adverse effects increase, including addiction and overdose, depression and neuroendocrine dysfunction.[14]As opioid doses increase patients are also likely to experience

[10] Martin WR, Jasinski DR. (1969) Physiological parameters of morphine dependence in man--tolerance, early abstinence, protracted abstinence. *J Psychiatr Res*., 7(1), 9-17 DOI: 10.1016/0022-3956(69)90007-7

[11] Erin Krebs, Effect of Opioid vs Nonopioid Medications on Pain-Related Function in Patients With Chronic Back Pain or Hip or Knee Osteoarthritis Pain: The SPACE Randomized Clinical Trial, (2018) 319(9), 872-882. doi:10.1001/jama.2018.0899; Jason Busse. (2018). Opioids for Chronic Noncancer Pain A Systematic Review and Meta-analysis. *JAMA* 320(23), 2448-2460. doi:10.1001/jama.2018.18472); National Academies of Science, Engineering and Medicine, *Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use* 17 (Phillips, et al. eds., 2017) (hereinafter, "NASEM, *Pain Management and the Opioid Epidemic*").

[12] Naliboff BD, et al. (2011). A randomized trial of 2 prescription strategies for opioid treatment of chronic nonmalignant pain. *J Pain*,12(2), 288–96. doi: 10.1016/j.jpain.2010.09.003

[13] Dowell D, et al. (2016). CDC guideline for prescribing opioids for chronic pain—United States, 2016. *JAMA*, 315(15), 1624-1645. doi:10.1001/jama.2016.1464

[14] Centers for Disease Control and Prevention (CDC). Vital signs: Overdoses of prescription opioid pain relievers and other drugs among women—United States, 1999–2010. *MMWR* Morb Mortal Wkly Rep 2013, 62(26), 537–542; Baldini A. et al. (2012). A review of potential adverse effects of long-term

sedation and a decreased level of functioning. Many patients on long-term opioids are not doing well. A large observational study of long-term opioids found that four out of five chronic pain patients taking opioids continued to experience significant pain and dysfunction.[15] In the study, middle-aged women, a target market for the opioid industry, experienced especially poor outcomes.

In fact, not only is credible evidence lacking to support claims of effectiveness, evidence suggests that chronic use of opioids can even make pain worse, a phenomenon called hyperalgesia.[16]

Finally, one of the primary limitations to daily, long-term opioid use is the development of tolerance. When opioids are taken daily, the patient rapidly becomes tolerant to the pain-relieving effects. To maintain pain relief, the dose must be increased.[17] As opioid doses rise, the risk of serious adverse effects increase, including addiction, neuroendocrine dysfunction, sedation, respiratory depression and death. Additionally, tolerance to the euphoric or analgesia effects of opioids develops more quickly than tolerance to the respiratory depression effect, putting users at a serious risk of overdose.[18]

2. There has been a sharp increase in the prevalence of opioid addiction, abuse, overdose and death in the United States, in West Virginia and in Cabell County and the City of Huntington. The increased prevalence of opioid addiction has resulted in an array of health and social problems commonly referred to as "the Opioid Epidemic."[19]

opioid therapy: A practitioner's guide. *Prim Care Companion CNS Disord*, 14(3), pii. doi: 10.4088/PCC.11m01326

[15] LeResche L. et al. (2015). Sex and Age Differences in Global Pain Status Among Patients Using Opioids Long Term for Chronic Noncancer Pain. *J Womens Health (Larchmt)*, 24(8), 629-635. doi: 10.1089/jwh.2015.5222

[16] Compton, P., et al. (2003). Withdrawal Hyperalgesia After Acute Opioid Physical Dependence in Nonaddicted Humans: A Preliminary Study. *The Journal of Pain* (4)9, 511-519. doi: 10.1016/j.jpain.2003.08.003

[17] Volkow, N., et al. (2016). Opioid Abuse in Chronic Pain-Misconceptions and Mitigation Strategies. *N. Engl. J. Med*., (374), 1253, 1256. doi: 10.1056/NEJMra1507771

[18] *Id.* (citing Hill, R. et al. (2016). Ethanol Reversal of Tolerance to the Respiratory Depressant Effects of Morphine. *Neuropsychopharmacology*, (41)(3), 762-73. doi: 10.1038/npp.2015.201; GS. et al. (1989). Differential Development of Acute Tolerance to Analgesia, Respiratory Depression, Gastrointestinal Transit and Hormone Release in a Morphine Infusion Model. *Life Sci*., 45(18), 1627-36. 0.1016/0024-3205(89)90272-5

[19] I have reviewed the Expert Report of Kathleen Keyes, Ph.D. and the data, studies and statistics regarding prevalence further form the basis for my opinion herein. I will therefore not restate the data, studies and evidence Dr. Keyes discusses here.

In the 1980s and early 1990s, the incidence of opioid addiction in the United States was relatively low and deaths from opioid overdose mainly occurred in poor, urban communities with a high prevalence of heroin addiction.

Beginning in the early 1980s, however, a campaign against conservatism in opioid prescribing began to take place.[20] In a 1980 *New England Journal of Medicine* letter by Jane Porter and Dr. Hershel Jick, the authors found only four "reasonably well documented cases of addiction" among nearly 12,000 hospitalized patients with no history of addiction who had received any narcotic preparation.[21] While Porter and Jick had only looked at medical records for hospitalized patients, Purdue starting using the study to claim that less than one percent of patients treated with opioids became addicted.[22] In turn, Pain specialists routinely cited it in their lectures.[23] Pain management specialists, including Dr. Kathleen Foley, presented Porter and Jick's findings as evidence that "medical use of opioids is rarely associated with the development of addiction."[24] In 1986, a paper written by Dr. Russell Portenoy and Kathy Foley, who were to become prominent "key opinion leaders" for the opioid industry, described the treatment of 38 chronic pain patients and concluded that opioid pain relievers could be prescribed safely on a long-term basis.[25] Despite its low-quality evidence, the paper was widely cited to support expanded use of opioids for chronic non-cancer pain. The paper also failed to disclose that Drs. Portenoy and Foley had financial ties to Purdue Pharma.

Industry joined together to dramatically expand the overall market for opioids far beyond its legitimate use for acute pain, cancer pain, palliative care and catastrophic injury. Specifically, industry orchestrated a multi-faceted misinformation campaign that included false medical "consensus" through paid and co-opted "experts" and specialty "professional" groups to give the medical community at large the impression that "the experts" endorsed widespread opioid use and to create doubt regarding what science and evidence had shown for centuries. Industry created "patient advocacy groups" and funded professional organizations to spread the false message that fear of aggressive opioid prescribing was irrational "opiophobia" and was a barrier

[20] In additional to documents and publications cited herein, additional documents supporting my opinions in this Section are contained at Schedule 4 to this Report.

[21] Porter J, Jick H. (1980). Addiction Rare in Patients Treated with Narcotics. *New England Journal of Medicine* 302(2), 123. doi: 10.1056/nejm198001103020221

[22] Zhang, S. *The One-Paragraph Letter From 1980 That Fueled the Opioid Crisis*, The Atlantic (June 2, 2017), *available at, https*://www.theatlantic.com/health/archive/2017/06/nejm-letter-opioids/528840/.

[23] *Id.*

[24] Ny, L. (Ed.). (1981). *New Approaches to Treatment of Chronic Pain: A Review of Multidisciplinary Pain Clinics and Pain Centers*, Washington: D.C., Government Printing Office, at 169-181, *available at* https://archives.drugabuse.gov/sites/default/files/monograph36.pdf.

[25] Portenoy RK, Foley KM. (1986). Chronic use of opioid analgesics in non-malignant pain: report of 38 cases. *Pain* 25(2), 171–86. doi: 10.1016/0304-3959(86)90091-6

to compassionate treatment of pain.[26] They worked through organizations that directly impact clinical care like the Joint Commission and the Federation of State Medical Boards, to create a new standard of care where all pain must be assessed and treated and where clinicians must prescribe opioids or suffer negative professional ramifications. Armed with this phony "consensus" and the new "standards," the opioid industry then deployed massive armies of sales representatives, "educational programming," and "literature" to spread that "consensus" and these new "standards" across the country.

Industry's message was spread to medical schools in the late in the 1990s. I experienced this messaging first-hand in my medical training. As I explained in a 2010 interview, "[i]f patients have legitimate pain, we were taught that they don't become addicted to these medicines, and that instead of allowing people to suffer needlessly, we should be much more liberal in our prescribing of opioids."[27]

Some notable events in the opioid industry's misinformation campaign, included:

- In 1995, the president of the American Pain Society (APS), an industry front group, introduced a campaign entitled "Pain is the Fifth Vital Sign" at the society's annual meeting. This campaign encouraged health care professionals to assess pain with the "same zeal" as they do with vital signs and urged more aggressive use of opioids for chronic non-cancer pain.[28] Shortly thereafter, the Veterans' Affairs health system, as well as the Joint Commission, which accredits hospitals and other health care organizations, embraced the "Pain is the Fifth Vital Sign" campaign to increase the identification and treatment of pain, especially with opioid pain relievers.[29]

- With MS Contin's patent set to expire in 1996, Purdue patented in 1993, and marketed in 1996, Oxycontin – an oxycodone analgesic that purportedly modulated opioid highs and lows to provide ongoing pain relief, eliminating the temptation to increase the amount or

[26] Kolodny A, et al. (2015). The prescription opioid and heroin crisis: a public health approach to an epidemic of addiction. *Annu Rev Public Health,* 36, 559-74. doi: 10.1146/annurev-publhealth-031914-122957; U.S. Senate Homeland Security & Governmental Affairs Committee. (Feb. 2018). *Fueling an Epidemic, Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*, U.S. Senate, at 1, *available at*, https://www.hsgac.senate.gov/imo/media/doc/REPORT-Fueling%20an%20Epidemic-Exposing%20the%20Financial%20Ties%20Between%20Opioid%20Manufacturers%20and%20Third%20Party%20Advocacy%20Groups.pdf; *see also* Schedule 4.

[27] *Long-Term Opioid Therapy Reconsidered* (interviews).

[28] Campbell, JN. (1996). APS 1995 presidential address. *Pain Forum* 5:85–88.

[29] Kolodny A, et al. (2015). The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction. *Annu. Rev. Public Health*, 36, 559-74. doi: 10.1146/annurev-publhealth-031914-122957

frequency of doses.[30] Prior to the introduction of OxyContin, many physicians were reluctant to prescribe opioid pain relievers on a long-term basis for common chronic conditions because of their concerns about addiction, tolerance, and physiological dependence.[31] To overcome what they claimed to be "opiophobia," physician-spokespersons for opioid manufacturers published papers and gave lectures in which they claimed that the medical community had been confusing addiction with "physical dependence." They described addiction as rare and completely distinct from so-called "physical dependence," which was said to be "clinically unimportant."[32]

- By May 1996, Purdue had initiated or planned nineteen "OxyContin Wholesaler Special Programs." Three distributors, Bergen Brunswig Corporation (which in 2001 merged with AmeriSource Health to become AmericsourceBergen Corporation), Cardinal Health, and McKesson were to receive over 82 percent of Purdue's initial expenditure for rebates, telemarketing, and screen-saver advertising.[33] In June 1996, Guerdon R. Green, executive director of Purdue's National Accounts and Trade Division, thanked the wholesalers for "the assistance the active NWDA [National Wholesale Druggists' Association] members gave us in the marketing of this product."[34] In 1996, the rate of opioid use began accelerating rapidly.[35] This acceleration was fueled in large part by the introduction of OxyContin.

- In 1997, the APS and American Academy of Pain Medicine (AAPM), two industry front groups, issued a "consensus statement" that claimed: (1) "the de novo development of addiction when opioids are used for the relief of pain is low"; (2) side effects were either easily treated or "usually dissipate with continued use"; (3) "tolerance has not proven to be a prevalent limitation to long term opioid use"; (4) what appears as "tolerance is usually progression of disease"; (5) "for most opioids, there does not appear to be an arbitrary upper dosage limit, as was previously thought"; and (6) "that respiratory

[30] Harriet Ryan, Lisa Girion & Scott Glover, *'You Want a Description of Hell:' OxyContin's 12-Hour Problem*, Los Angeles Times (May 5, 2016), *available at* https://www.latimes.com/projects/oxycontin-part1/.

[31] Turk, DC, et al. (1994). Physicians' attitudes and practices regarding the long-term prescribing of opioids for non-cancer pain. *Pain,* 59(2), 201–208. doi: 10.1016/0304-3959(94)90072-8

[32] Portenoy RK. 1996. Opioid therapy for chronic nonmalignant pain: clinicians' perspective. *J. Law Med. Ethics,* 24(4), 296–309. doi: 10.1111/j.1748-720x.1996.tb01871.x

[33] PKY181732374.

[34] PDD1701421278.

[35] International Narcotics Control Board (INCB). (2007). *The Report of the International Narcotics Control Board for 2007*. Vienna: INCB. United Nations.

depression induced by opioids tends to be a short-lived phenomenon, generally occurs only in the opioid-naive patient, and is antagonized by pain." [36]

- In April 1998, the Federation of State Medical Boards (FSMB) approved model guidelines for the use of controlled substances in treating pain. The core message was that pain was undertreated and that state medical boards should, in cooperation with state attorneys general, ease regulatory restrictions that "impede the effective use of opioids to relieve pain."[37] The guidelines were written with the help of unspecified contributions to APS and AAPM, among other organizations. The 1998 guidelines were widely distributed to state medical boards, medical professional organizations, other health care regulatory boards, patient advocacy groups, pharmaceutical companies, state and federal regulatory agencies, and practicing physicians and other health care providers.

As a result of these activities and a well-coordinated industry campaign between the opioid manufacturers and distributors (*see* Section VI(4)), below, opioid use began to soar in the 1990s.[38] Significantly, however, such growth could not have occurred without the assistance of the wholesalers who distributed the drugs. As detailed below, McKesson, Cardinal, and AmerisourceBergen, known as the "Big Three," used various marketing tools to promote opioid analgesics and the revisionist message of liberalized prescribing that fostered sales and addiction. In the mid-1990s, the distributors assumed an active role and continued to expand their role over the next two decades (*see* Section VI(4)). Distributors did more than simply ship orders, but rather sold services designed to increase demand, including drafting template letters, establishing programs on how pharmacists could advise and reassure patients about opioids, and placing in-pharmacy digital advertisements to appeal to customers.

In fact (as discussed in Sections VI(4) below), Defendants were Purdue and other opioid manufacturer's essential business partners in growing demand for prescription opioids. From the beginning, Purdue recognized the need to involve the Defendants in the campaign to grow the prescription opioid market, noting that "over 80% of the current drug market [was] controlled by four players: McKesson, Bergen, Cardinal, and AmeriSource."[39] Purdue recognized that "[c]ontacts [with distributors] will facilitate us moving effortlessly through the organization."[40]

[36] Haddox, JD. et al. (1997). "The Use of Opioids for the Treatment of Chronic Pain: A Consensus Statement from the American Academy of Pain Medicine and the American Pain Society." *Clinical Journal of Pain* 13, 6-8.

[37] FSMB, "Model Policy for the Use of Controlled Substances for the Treatment of Pain," *available at* https://dprfiles.delaware.gov/medicalpractice/Model_Policy_Treatment_Pain.pdf

[38] *See also* Schedule 4.

[39] PKY181715440 at 442.

[40] *Id.* at 443.

In Purdue's pre-launch meeting notes, it was clear the Defendants were to play a major role in increasing the supply of Oxycontin.[41]

Through the early years of Oxycontin's promotion, Defendants played a critical role in the marketing of the product.[42] Cardinal telemarketers promoted OxyContin to pharmacies in early 1996, and, in 1997, provided "DSP Marketing Points" to opioid manufacturers who signed distribution deals.[43] AmerisourceBergen and its predecessor, Bergen Brunswig, offered similar services, as well used its Accusource System to push customers pharmacy customers to Purdue's Oxycontin brand rather than its competition.[44] By the early 2000s, Purdue agreed to market OxyContin through PlusCare, Bergen's managed care business. Using cover letters bearing the PlusCare and Good Neighbor Pharmacy logos, Bergen dispatched customized document mailings to more than 1,800 members of its national pharmacy network, after which Purdue sent sales representatives to the same pharmacies "to make sure a) they received the information b) would they like additional information c) make sure that they are stocking OxyContin d) make the pharmacist aware of who the high prescribers of opioids are in the area e) inform the provider that this particular 'Good Neighbor Pharmacy' stocks OxyContin and f) further educate the pharmacist on proper pain management."[45] Joseph Hennessy, a Purdue senior area manager for managed care, wrote that these mailings "provide[] us a good opportunity to educate pharmacists on proper pain management and why OxyContin is appropriate. They in turn can help educate patients on why this medicine is appropriate vs. questioning why the patient is prescribed."[46]

This was only the beginning. As detailed in Sections VI(4) below, Defendants and opioid manufacturers worked in a coordinated and vertically integrated supply chain that worked together to grow the market for prescription opioids through a variety of methods.[47]

Not only did opioid manufacturers and Defendants work together with one goal, "to sell product,"[48] but the opioid industry cooperated and coordinated through three main overlapping

[41] PKY180255278

[42] *See e.g.* PKY180255278; PDD8801142910; PKY180256902; PPLPC030000271126; PPLPC009000007590; PPLPC029000022136; PDD8801281191; PPLPC008000013580; PPLPC004000145999; PPLPC004000146529; PKY181284712.

[42] PPLPC029000022136; PDD8801281191; PPLPC008000013580; PPLPC004000145999; PPLPC004000146529.

[43] PDD1706044077; PDD1701383797.

[44] PDD8801142910

[45] PPLPC035000003770.

[46] PPLPC034000102543; *see also* PPLPC029000022136; PDD8801281191.

[47] *See also* Expert Report of Jakki Mohr, Ph.D.

[48] MCKMDL00543971 at 972; *see also* Expert Report of Jakki Mohr, Ph.D.

organizations (the Pain Care Forum, the HDA and the National Association of Chain Drug Stores ("NACDS")) to coordinate their campaign to dramatically increase demand for prescription opioids, maintaining supply and enabling unfettered access to the prescription opioids they were selling (*see also* SectionVI(4)(a)(5), below). These organizations brought together the key players in the industry misinformation campaign. For example, the Pain Care Forum included opioid manufacturers, key front groups used to disseminate misinformation like the APS, AAPM and APF, the HDA (distributors association) and the FSMB, a key player in adopting guidelines to change medical practice towards accepting opioids for widespread use.[49] Similarly, industry including opioid distributors and affiliate member opioid manufacturers combined within the forum of the HDA to advance the goals of the opioid industry.[50] These groups and their members often trumpeted the opioid industry messages, without disclosing their industry funding. Indeed, as when the United States Senate investigated some of the front groups in 2018, the Committee found that they "often echoed and amplified messages favorable "to increased opioid use- and ultimately, the financial interests of opioid manufacturers."[51] According to the Senate, "these groups have issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain, lobbied to change laws directed at curbing opioid use, and argued against accountability for physicians and industry executives responsible for over prescription and misbranding."[52]

Based on my review of documents, testimony, literature and my professional experience, it is clear to me that the opioid industry worked to create and maintain an inaccurate perception of opioid risks and benefits to influence the medical community, the public, regulators, professional governing bodies and standards organizations and did so in part through front groups including those described herein, those described in the United States Senate's Homeland Security and Governmental Affairs Committee Report, *Fueling an Epidemic, Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*, (2018).[53]

[49] Burt Rosen [Purdue] Deposition (January 16, 2019) at 59:23-60:13; Rosen Ex 1. PPLP004272094 at 096.

[50] See generally, Patrick Kelly [HDA] Deposition (May 10, 2019) at 332:2-347:23 (discussing Ex. 35 (CAH_MDL2804_01110712)that describes HDA's task force functions that include DEA communications, lobbying, legislative activity and media campaigns); John Gray [HDA] Deposition (July 30, 2020) at 79:16-25.

[51] U.S. Senate. *Fueling an Epidemic, Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*, U.S. Senate Homeland Security and Governmental Affairs Committee, Minority Staff Report (Feb. 2018), *available at* https://www.hsgac.senate.gov/imo/media/doc/REPORT-Fueling%20an%20Epidemic-Exposing%20the%20Financial%20Ties%20Between%20Opioid%20Manufacturers%20and%20Third%20Party%20Advocacy%20Groups.pdf. (hereinafter "U.S. Senate. *Fueling and Epidemic*").

[52] *Id.*

[53] *See also* Schedule 4 to this Report.

Industry coordinated and promoted the false messages through these groups and their member organizations to falsely portray that there was a new medical "consensus" that opioids could be widely used for any duration to treat non-cancer pain and that all pain needed to be treated. As Richard Sackler, President of Purdue Pharma, acutely, observed, accomplishing a wide spread change in opioid prescribing, and thus sales, had to be done through a multi-faceted and coordinated effort and that "the fate of our products [is] inextricably bound with the pain movement."[54] The "pain movement," however, was funded by, and made up of industry.[55] Pain Care Forum members alone were reported to have spent $900 million in lobbying state and federal policymakers.[56] Funding was often well hidden. As addressed by one industry front group head (the Wisconsin Pain and Policy Studies Group), when asked about the group's influence: "I'm impressed that you could detect our fingerprints... I'll wear gloves next time."[57]

It is not a surprise that starting in the late 1990s there was sharp and steady climb in the incidence of opioid addiction and opioid-related overdose deaths, climbing to a level that prompted the CDC to call to call the crisis the "worst drug overdose epidemic in [US] history" and note that the primary driver was an unprecedented increase in prescription opioid consumption.[58] Indeed, from 1997 to 2012 there was a 900% increase in individuals seeking treatment for addiction to prescription opioids.[59] During this same time frame, the rate of opioid-related overdose deaths nearly quadrupled.[60]

Accidental opioid overdose is a common cause of death in individuals suffering from opioid addiction.[61] Consistent findings in samples of prescription overdose decedents show that deaths

[54] PPLPC045000004928 at 929.

[55] *See e.g.* U.S. Senate. *Fueling and Epidemic.*

[56] Perrone, M. and Wieder, B. *Pro-painkiller echo chamber shaped policy amid drug epidemic*. Associated Press (Sept. 19, 2016), *available at* https://publicintegrity.org/state-politics/pro-painkiller-echo-chamber-shaped-policy-amiddrug-epidemic/

[57] WIS_PPSG_000036.

[58] Paulozzi, LJ. (2010). *The epidemiology of drug overdoses in the United States*. Grand Rounds Lecture Presented at Maimonides Med. Cent. Dep. Psychiatry, Brooklyn, New York.

[59] SAMHSA (Subst. Abuse Ment. Health Serv. Adm.). 2010. *Center for Behavioral Health Statistics and Quality. Treatment Episode Data Set* (*TEDS*)*: 2007. Discharges from Substance Abuse Treatment Services*. DASIS Ser.: S-51, HHS Publ. No. (SMA) 10-4479. Rockville, MD: SAMHSA; SAMHSA (Subst. AbuseMent. Health Serv. Adm.). 2013. *Center for Behavioral Health Statistics and Quality. Treatment Episode Data Set* (*TEDS*)*: 2001–2011. National Admissions to Substance Abuse Treatment Services*. BHSIS Ser. S-65, DHHS Publ. No. SMA 13-4772. Rockville, MD: SAMHSA.

[60] Chen, LH. et al. (2014). *Drug-Poisoning Deaths Involving Opioid Analgesics: United States, 1999–2011*. NCHS Data Brief No. 166. Hyattsville, MD: Natl. Cent. Health Stat.

[61]Hser YI, Hoffman V, Grella CE, Anglin MD. (2001). A 33-year follow-up of narcotics addicts. *Arch. Gen. Psychiatry*, 58(5), 503–8. doi: 10.1001/archpsyc.58.5.50
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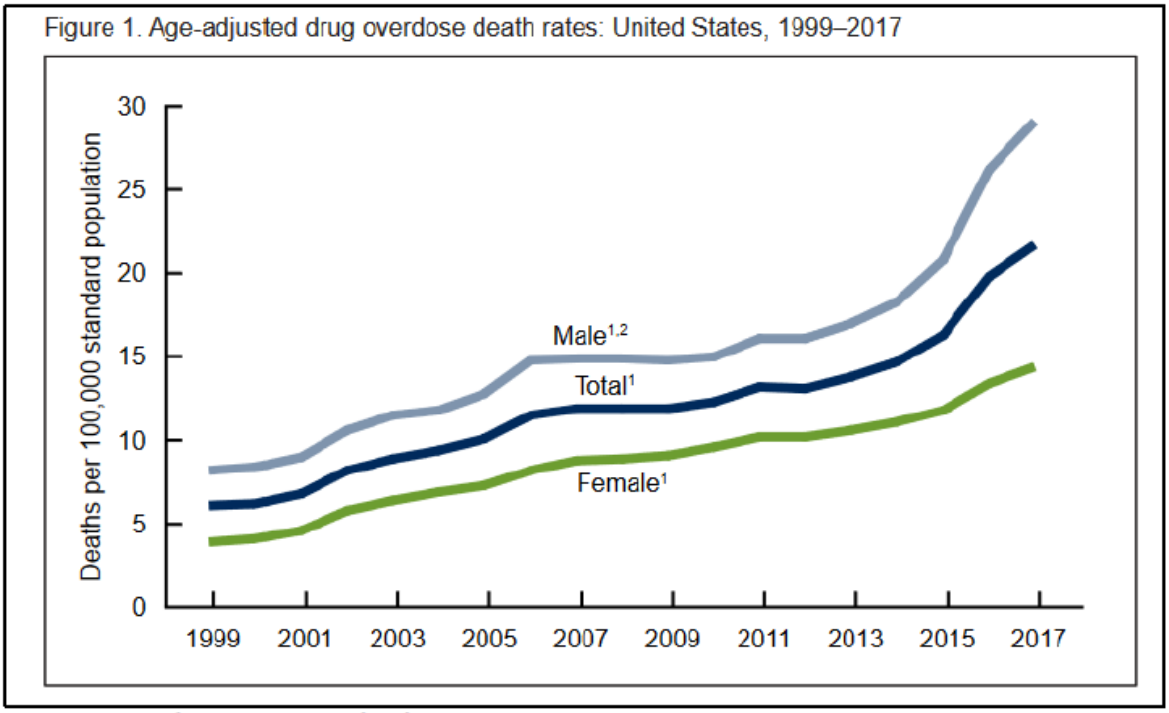
are most common in individuals likely to be suffering from opioid addiction.[62] For example, a study of 295 unintentional prescription overdose deaths in West Virginia found that four out of five decedents (80%) had a history of a substance use disorder.[63] The sharp increase in the prevalence of opioid addiction is a key driver of opioid-related morbidity and mortality.

As addiction to prescription opioids increased, so did overdose and death. According to the CDC, and as illustrated in the chart below, the "age-adjusted rate of drug overdose deaths increased from 6.1 per 100,000 standard population in 1999 to 21.7 in 2017:"[64]



Source: Centers for Disease Control and Prevention

[62] Kolodny, A. et al. (2015). The prescription opioid and heroin crisis: a public health approach to an epidemic of addiction. *Annu Rev Public Health*, 36, 559-574. https://doi.org/10.1146/annurev-publhealth-031914-122957; Hall, AJ. et al. (2008). Patterns of abuse among unintentional pharmaceutical overdose fatalities. *JAMA* 300(22), 2613–20. doi: 10.1001/jama.2008.802; Johnson EM, Lanier WA, Merrill RM, Crook J, Porucznik CA, et al. 2013. Unintentional prescription opioid-related overdose deaths: description of decedents by next of kin or best contact, Utah, 2008–2009. *J. Gen. Intern. Med.*, 28(4), 522–29. doi: 10.1007/s11606-012-2225-z9

[63] Kolodny, A. et al. (2015). The prescription opioid and heroin crisis: a public health approach to an epidemic of addiction. *Annu Rev Public Health*, 36, 559-574. https://doi.org/10.1146/annurev-publhealth-031914-122957

[64] Report by the United States House of Representatives Energy and Commerce Committee, *Red Flags and Warning Signs Ignored: Opioid Distribution and Enforcement Concerns in West Virginia,* December 19, 2018 at 23 (hereinafter "Congressional Report"); *citing* Centers for Disease Control and Prevention, Drug Overdose Deaths in the United States, 1999-2017, NCHS Data Brief (Nov. 2008) available at https://www.cdc.gov/nchs/data/databriefs/db329-h.pdf.

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Between 1999 and 2016, 351,000 lives were lost to opioid overdose.[65] In 2017, the CDC announced that the United States life expectancy had actually declined in the last several years, due to the increase in drug overdose deaths:

> The latest CDC data show that the U.S. life expectancy has declined over the past few years. Tragically, this troubling trend is largely driven by deaths from drug overdose and suicide. Life expectancy gives us a snapshot of the Nation's overall health and these sobering statistics are a wakeup call that we are losing too many Americans, too early and too often, to conditions that are preventable.[66]

The rise in opioid consumption and addiction has also been associated with a sharp increase in emergency room visits for nonmedical prescription opioid use[67] and in neonatal abstinence syndrome.[68]

Defendants internal documents recognize that the opioid pills they supplied have caused a "national epidemic."[69] Indeed, as Defendant McKesson observed in internal documents, by 2013:[70]

- More than 45 people were dying per pay in this country from prescription opioids;
- Each year from 1999 to 2010 that death toll rose (from 4,030 in 1999 to 16,651 in 2010 alone);
- By 2013, 1 in 20 people in the U.S. reported using prescription opioids non-medically in the past year;
- By 2012, there were 6,700 new prescription opioid users per day;

[65] Centers for Disease Control and Prevention, Data Brief 294. Drug Overdose Deaths in the United States, 1999- 2016, *available at* https://www.cdc.gov/nchs/data/databriefs/db294_table.pdf#page=4.

[66] Centers for Disease Control and Prevention. Press Release: CDC Director's Media Statement on U.S. Life Expectancy (Nov. 29, 2018) *available at* https://www.cdc.gov/media/releases/2018/s1129-US-life-expectancy.html

[67] SAMHSA (Subst. Abuse Ment. Health Serv. Adm.). (2013). *Drug Abuse Warning Network, 2011: National Estimates of Drug-Related Emergency Department Visits*. DHHS Publ. No. SMA 13-4760, DAWN Ser. D-39. Rockville, MD: SAMHSA.

[68] Patrick, SW, et al. (2012). Neonatal abstinence syndrome and associated health care expenditures: United States, 2000–2009. *JAMA*, 307(18), 1934-40. doi: 10.1001/jama.2012.3951

[69] MCK-AGMS-006-0000903; MCKMDL00407451

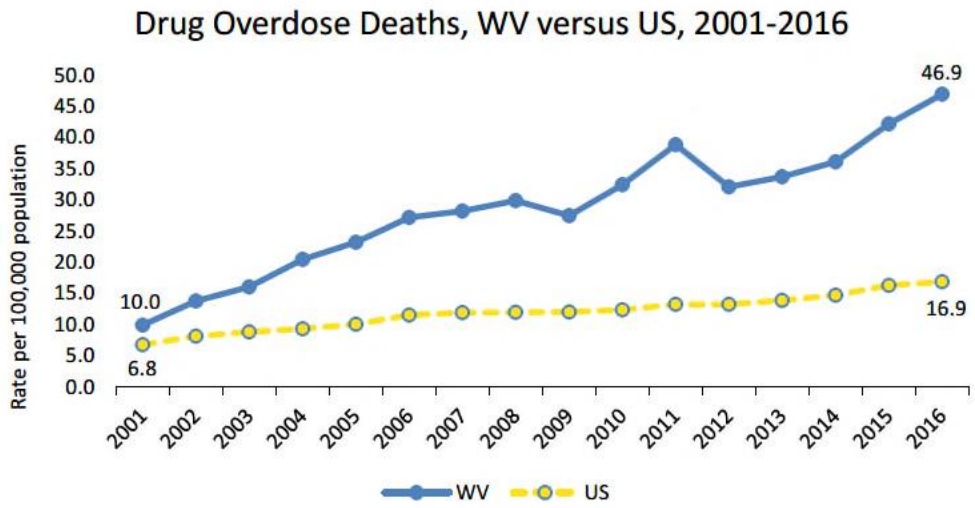
[70] MCK-AGMS-006-0000903

- The economic impact to America was greater than $57 billion dollars per year.

Internally. McKesson recognized that the prescription Opioid Epidemic (that McKesson termed "the pill spill") dwarfed other historical disasters, including the BP oil spill.[71]

West Virginia has been accurately characterized as "ground zero" in the opioid crisis. As an investigation by the United States House of Representatives Energy and Commerce Committee found, "[t]he sudden influx of prescription opioids, leading to the resulting increases in abuse and addiction, has had profound effects on West Virginia."[72] A study published in the Journal of the American Medical Association in December 2008 found that, in 2006, 93 percent of the unintentional overdose deaths attributable to prescription drugs in West Virginia involved opioids.[73] The study also found that 63 percent of the overdose deaths were associated with pharmaceutical diversion, and 21 percent exhibited evidence of doctor shopping.[74] The study also noted "[t]he Drug Enforcement Administration confirms that drug diversion was widespread in West Virginia and the Appalachian region during this period."[75]

Deaths from drug overdose in West Virginia exceed the national average:[76]



[71] *See* MCK-AGMS-006-0000896- MCK-AGMS-006-0000897.

[72] Congressional Report at 25.

[73] Hall, A., et al. (2008). Patterns of Abuse Among Unintentional Pharmaceutical Overdose Fatalities, *JAMA*, (300)(22), 2613, 2619. doi: 10.1001/jama.2008.802

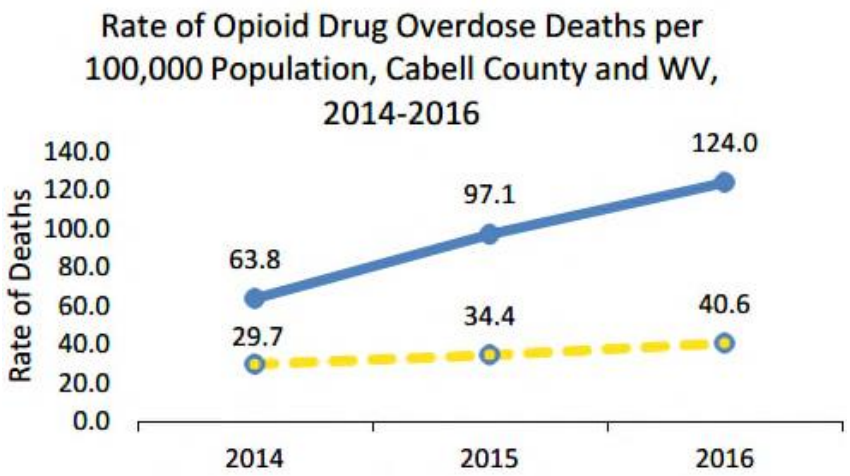
[74] *Id*. at 2616.

[75] *Id.* at 2619; *citing* Drug Market Analysis 2008: Appalachia High Intensity Drug Trafficking Area, a Report by DOJ National Intelligence Center (2008).

[76] Source: West Virginia Board of Pharmacy, *Prescription Opioid Problematic Prescribing Indicators County Report: Cabell County*, October 2017

West Virginia has had the highest age-adjusted rate of opioid-related overdose deaths in the nation,[77] a fact Defendants were well aware of and acknowledged in internal documents.[78] In 2017, there were 833 drug overdose deaths involving opioids in West Virginia—a rate of 49.6 deaths per 100,000 persons. This is double the rate in 2010 and threefold higher than the national rate of 14.6 deaths per 100,000 persons.[79] While the national rate of drug overdose deaths increased 149% from 2001 to 2016, West Virginia saw a 316% increase, with most overdose deaths involving at least one opioid.[80]

The Cabell- Huntington Community is one of the hardest hit communities. The rate of drug overdose deaths in Cabell County exceeds the state average:[81]



[77] Centers for Disease Control and Prevention, Drug Overdose Deaths in the United States, 1999-2017, NCHS Data Brief (Nov. 2008) available at https://www.cdc.gov/nchs/data/databriefs/db329-h.pdf.

[78]MCKMDL00407451; MCKMDL00407477; MCKMDL00336347 at slides 26 & 115; MCKMDL0211520 (2014 Controlled Substances Flyer); ABDCMDL08366648; ABDCMDL00312630 (internal memo stating "West Virginia data: Highest opioid death rate in U.S."); ABDCMDL00310680 (HHS Press Release produced by AmerisourceBergen acknowledging the opioid crisis in West Virginia); CAH_FEDWV_00289109 at 116 ("West Virginia currently [2012] has prescription drug overdose rates (25.8%) nearly five times that of the state with the lowest rate (Nebraska us 5.5%)."); *see also*, CAH_FEDWV_00406037 (2016 West Virginia BOP Report.

[79] National Institute on Drug Abuse (NIDA), West Virginia Opioid Summary, June 13, 2019, *available at* https://www.drugabuse.gov/opioid-summaries-by-state/west-virginia-opioid-summary.

[80] W. Va. Dep't of Health and Human Res., 2016 West Virginia Overdose Fatality Analysis: Healthcare Systems Utilization, Risk Factors, and Opportunities for Intervention, at 9, Dec. 20, 2017 available at https://dhhr.wv.gov/bph/Documents/ODCP%20Reports%202017/2016%20West%20Virginia%20Overdose%20Fata lity%20Analysis_004302018.pdf.

[81] West Virginia Board of Pharmacy, *Prescription Opioid Problematic Prescribing Indicators County Report: Cabell County*, October 2017, available at https://helpandhopewv.org/docs/PFS_County_Reports/Cabell_PfS%20County%20Reports_Final.pdf.

In 2016, the rate of opioid overdose death in Cabell County was 124.0 per 100,000, compared to a rate of 40.6 per 100,000 in the state of West Virginia, and Cabell County had the highest opioid overdose death rate of any county in the state.[82] In 2016, Cabell County had the second highest opioid overdose death rate of any county in the nation.[83] In 2017, more people in Cabell County died of overdose than in any other West Virginia county. In 2018, Cabell County had the highest opiate overdose death rate of any county in the nation at 127.1 per 100,000.[84]

Overdose mortality is not the only adverse public health outcome associated with the opioid addiction crisis. The increased prevalence of opioid addiction has also led to an array of health and social problems in the United States and in West Virginia, including increasing use of heroin and fentanyl, increasing rates of injection-related infectious diseases, a negative impact on the work force, and soaring increases in neonatal abstinence syndrome and children entering foster care system.[85] These problems are described as occurring acutely in the Cabell-Huntington Community as follows:[86]

> Cabell County, WV, has been ravaged by the harmful effects of the substance use epidemic. This has culminated in increased drug activity, the highest rate of overdoses and overdose deaths our nation has seen, and poor health outcomes.
>
> Huntington readily recognized the severity of the issue seen in reported rates of overdose, overdose-associated deaths, and incidence of neonatal abstinence syndrome - the highest in the nation. The county has also been monitoring the sharp rise in the incidence of infections and other diseases associated with substance use, including hepatitis B and C, sexually transmitted infections, endocarditis, and most importantly - a recent HIV cluster.

[82] *Id.*

[83] Centers for Disease Control and Prevention. Multiple Cause of Death Data, *available at* https://wonder.cdc.gov/mcd.html.

[84] *Id.*

[85] Congressional Report at 25-26; Lynch S, Sherman L, Snyder SM, Mattson M. (2018). Trends in infants reported to child welfare with neonatal abstinence syndrome (NAS). *Child Youth Serv Rev*., 86(C), 135-141. doi: 10.1016/j.childyouth.2018.01.035; O'Donnell JK, Gladden RM, Seth P. (2017). Trends in deaths involving heroin and synthetic opioids excluding methadone, and law enforcement drug product reports, by census region—United States, 2006-2015. *MMWR Morb Mortal Wkly Rep*., 66(34), 897-903. doi: http://dx.doi.org/10.15585/mmwr.mm6634a2External; Paquette CE, Pollini RA. (2018). Injection drug use, HIV/HCV, and related services in nonurban areas of the United States: a systematic review. *Drug Alcohol Depend*, 188, 239-250. doi: 10.1016/j.drugalcdep.2018.03.049; Krueger AB. Where have all the workers gone? An inquiry into the decline of the US labor force participation rate. Brookings Papers on Economic Activity Conference, *available at* https://www.brookings.edu/bpea-articles/where-have-all-the-workers-gone-an-inquiry-into-the-decline-of-the-u-s-labor-force-participation-rate/, Published August, 2017.

[86] Resiliency Plan for Cabell County. In: Division of Addiction Sciences, ed. https://jcesom.marshall.edu/media/58477/2020_cabell-county-resiliency-plan_final.pdf2020.

> In Huntington, as heroin became more popular and widespread, and the rates of infectious diseases, overdose, and overdose death quickly increased, this culminated in a shocking outbreak of 27 overdoses in just four hours in the city of Huntington on August 15, 2016.

I have been provided with the deposition testimony of several witnesses from the Cabell-Huntington Community, a list of which is contained on Schedule 3 to my Report. These witnesses describe the devastation opioids have wrecked on the Cabell-Huntington Community. Some notable testimony includes:

- Jan Rader, Fire Chief for the City of Huntington, described the Opioid Epidemic in Huntington as "horrific," and stated that "There's not one person in this area that I know that has not been touched or had collateral damage to them, themselves from the … Opioid Epidemic. It is horrendous."[87] Rader describes the effect of the Opioid Epidemic on the community stating "This is a war zone. This is a war zone for first responders. It's a war zone for children. That's all they know growing up, is death and destruction."[88]

- Scott Lemley, former member of the City's Office of Drug Control Policy for the Huntington Police Department, testified that in 2015 "13.78 percent of the population of the County is addicted to something."[89] "[I]t's horrible. It has affected every aspect of what we do in Huntington from social – It's socioeconomic. It affects the University; it affects our medical community; it affects our quality of life and our parks; it affects our first responders; it affects our property values."[90]

- Chuck Zerkle Sheriff of Cabell County testified, "[l]ook around. Huntington is devastated with this. I can take you over here – backpackers, homeless, they're – I've got a friend that started out with a knee injury and ended up hooked on opioids, lost his family, lost his wife, lost everything because he started out with a doctor and ended up on heroin."[91]

- Gordon Merry, Director of Cabell County EMS described the devastation as "a very, very horrible experience. I wouldn't wish this on anybody. Medics have left. Going into houses where the mothers have overdosed and the kids are sitting there crying, wanting to know what wrong with their mother. It's mentally – and it's definitely taken its toll on the staff, turnovers, horrible. And it's not just EMS. It's police, fire, EMS and hospitals. It's answering the same call, or answering the call for the same person two to three times a day. It was a revolving door on top of the normal calls they had to answer. And the stress

[87] Jan Rader [Huntington] Deposition (June 17, 2020) at 78:23-79:3.

[88] *Id.* at 201:16-19.

[89] Scott Lemley [Huntington] Deposition (July 3, 2020), at 220:9-10.

[90] *Id.* at 303:14-20.

[91] Charles Zerkle [Cabell] Deposition (June 17, 2020), at 50:3-8.

level was very high."[92] …."Yes. I think they have gone above and beyond trying to save our community. Because it absolutely destroyed this community. I grew up here. I've been here 67 years. It's been devastating. My partner's daughter is dead because she overdosed. As I said, one of my employees. It's been devastating to us, to this community, to have this happen."[93]

- Steve Williams, Mayor of the City of Huntington, testified "I know that people are dying here. I know that the level of overdoses that we're having to deal with is causing a major disruption within our – within our community. I know it is a result of pills; I know it's a result of heroin; I know it's a result of other substances. We have babies that are being born exposed to substances; we have families that are being torn apart; we have parents who are dying. … My city is suffering, and I believe your clients are also responsible for the suffering that has been placed upon my community."[94]

Additionally, I have reviewed the expert reports of Kathleen Keyes, Ph.D. and Professor Thomas McGuire, Ph.D. The facts and data cited therein form additional basis for my opinions about the severity of the Opioid Epidemic in the Cabell-Huntington Community.

3. The increased prevalence of opioid addiction was caused by overexposing the United States population, especially people in the State of West Virginia, and in the Cabell-Huntington Community, to prescription opioids, and is still primarily driven by prescription opioids.

Over the past 25 years, the massive flood of prescription opioids into the United States, West Virginia and the Cabell-Huntington Community led to a public health catastrophe. From 1999 to 2011, consumption of hydrocodone in the United States more than doubled and consumption of oxycodone increased by nearly 500%.[95] By 2010 at its peak, Defendants were supplying hundreds of billions of MMEs of opioid narcotics into the United States:[96]

[92]Gordon Merry [Cabell] Deposition (June 29, 2020), at 36:9-20.

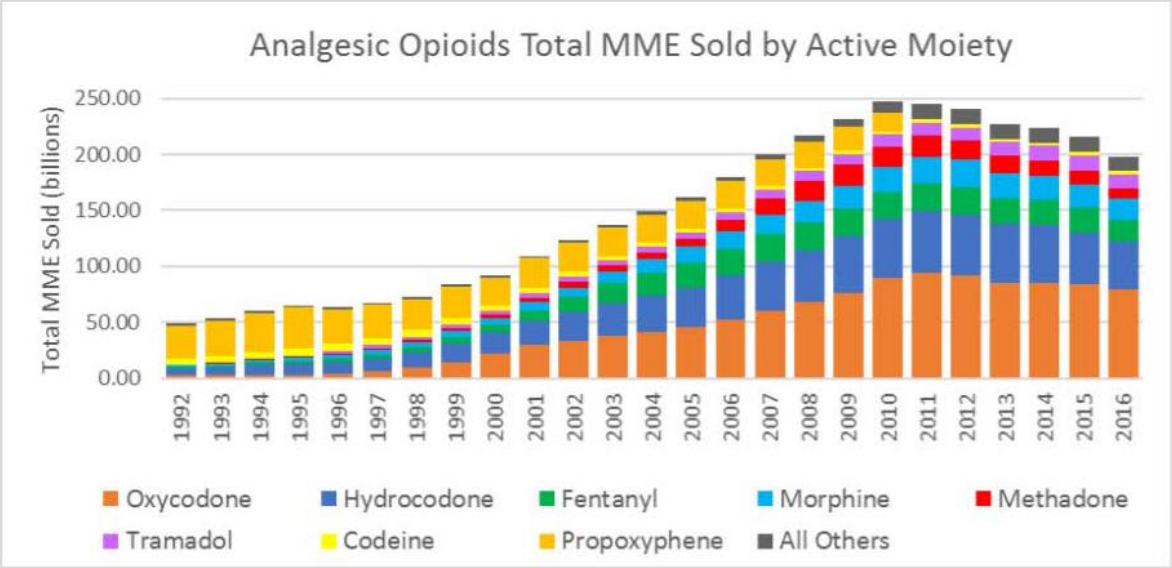
[93] *Id.* at 92:10-16.

[94] Steve Williams [Huntington] Deposition (June 30, 2020) at 49:6-15, 19-21.

[95] Jones, CM. 2013. *Trends in the distribution of selected opioids by state, US, 1999–2011*. Presented at Natl. Meet. Safe States Alliance, June 6, Baltimore, MD, *available at*, https://cdn.ymaws.com/www.safestates.org/resource/resmgr/imported/Jones.pdf.

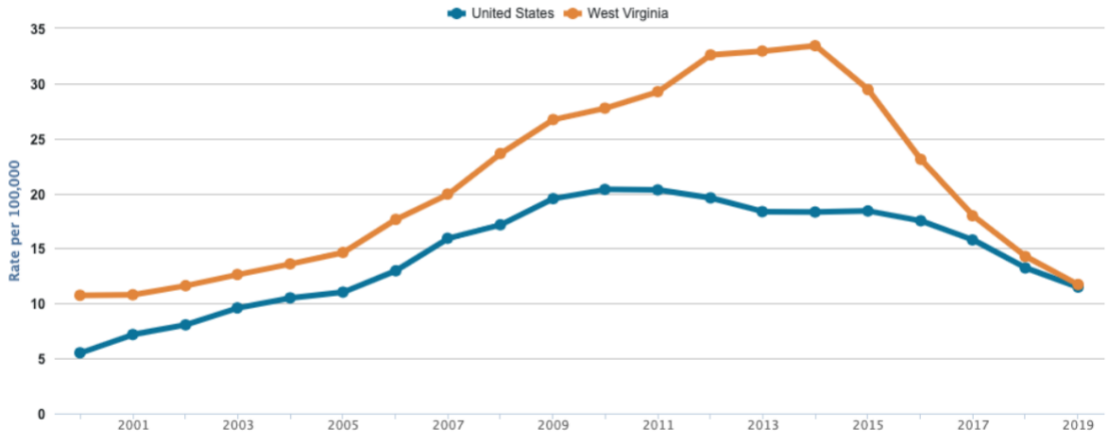
[96] *FDA Analysis of Long-Term Trends in Prescription Opioid Analgesic Products: Quantity, Sales, and Price Trends*, FDA, Mar. 1, 2018, *available at*, https://www.fda.gov/media/111695/download. https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM598899.pdf.

Figure 2: Total MMEs sold for aggregate opioid analgesic market – by active moiety



While the United States has far higher opioid consumption than any other country, opioid consumption in West Virginia far exceeded the national average. For example, in 2014 when the oxycodone supply into the state of West Virginia hit its peak, the state's rate of 33.4 kilograms of oxycodone per 100,000 people was 83% higher than the U.S. rate of 18.3 kilograms per 100,000 (Figure x).[97]

Oxycodone sales in kilograms per 100,000 people, West Virginia and United States



SHADAC analysis of U.S. Drug Enforcement Agency's Automated Reports and Consolidated Ordering System (ARCOS) Retail Drug Summary Reports.State Health Compare, SHADAC, University of Minnesota, statehealthcompare.shadac.org, Accessed July 28, 2020.

[97] SHADAC analysis of U.S. Drug Enforcement Agency's Automated Reports and Consolidated Ordering System (ARCOS) Retail Drug Summary Reports. State Health Compare, SHADAC, University of Minnesota, *available at*, statehealthcompare.shadac.org, Accessed July 28, 2020.

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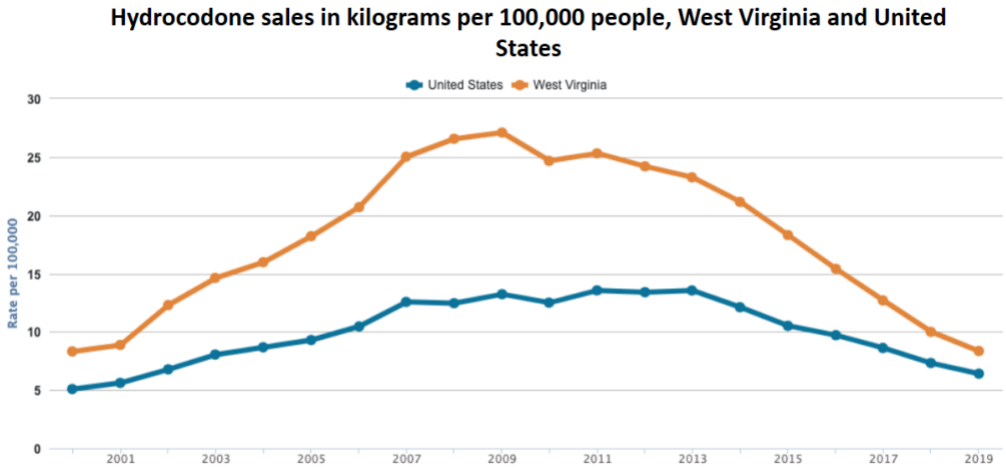
West Virginia also exceeded the exceptionally high national average for hydrocodone consumption. In 2009, the peak year for hydrocodone supply into West Virginia, the rate of 27.1 kilograms was 103% higher than the national average of 13.2 kilograms per 100,000 (Figure x).



SHADAC analysis of U.S. Drug Enforcement Agency's Automated Reports and Consolidated Ordering System (ARCOS) Retail Drug Summary Reports.State Health Compare, SHADAC, University of Minnesota, statehealthcompare.shadac.org, Accessed July 28, 2020.

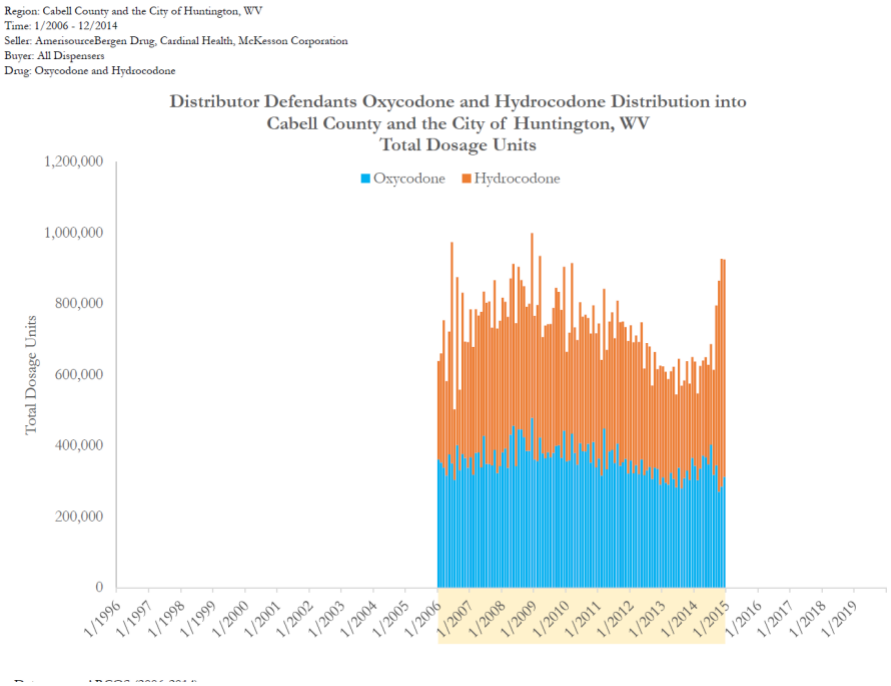
In 2013, the massive over-shipment amounts to enough hydrocodone and oxycodone to stock every home in the state of West Virginia with a pill bottle of opioids. With the flood of opioids into the state, it is not surprising that so many West Virginians became addicted and started dying in unprecedented numbers.

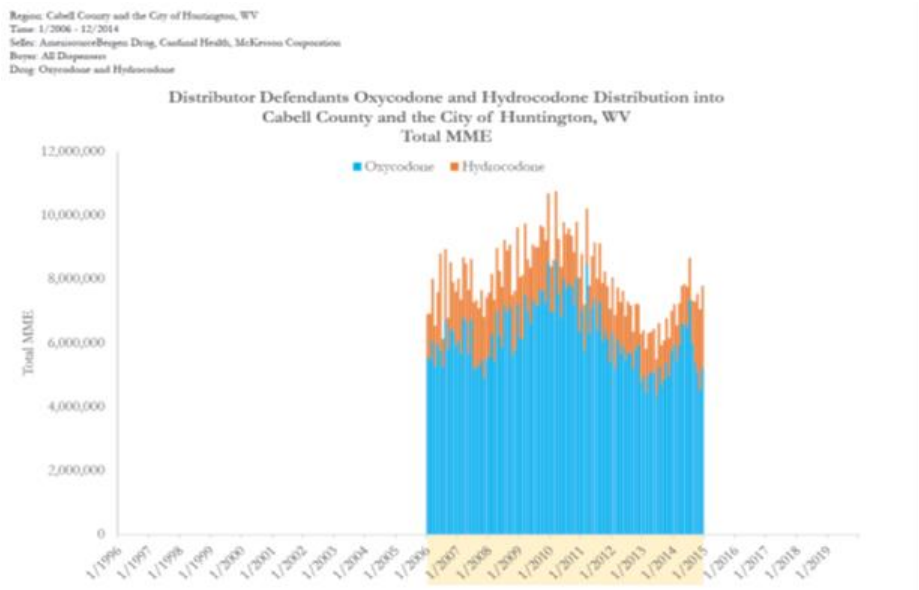
The Defendants also sent a wave of opioids into the Cabell-Huntington Community, exposing its population to the associated risks. As detailed in the Expert Report of Craig McCann, Ph.D., CFA, between 2005 and 2014, Defendants sent billions of MMEs into the Cabell Huntington Community of 99,946 people. In fact, between 2006 and 2014, dispensers in the Cabell-Huntington Community received 127.9 million Dosage Units or 3.3 billion MME of opioids, enough opioids for every resident in Cabell County and the City of Huntington, WV to consume 142 Dosage Units or 3,650 MME every year from 2006 to 2014.[98] The flood of Defendants' pills and MMEs into Cabell County is illustrated by Dr. McCann as follows (data for McKesson and ABDC was only produced starting in 2006):[99]

[98] Expert Report of Craig McCann at ¶ 17.

[99] *Id.* at Appendix 9 at p. 17- 18.

Confidential Subject to Protective Order



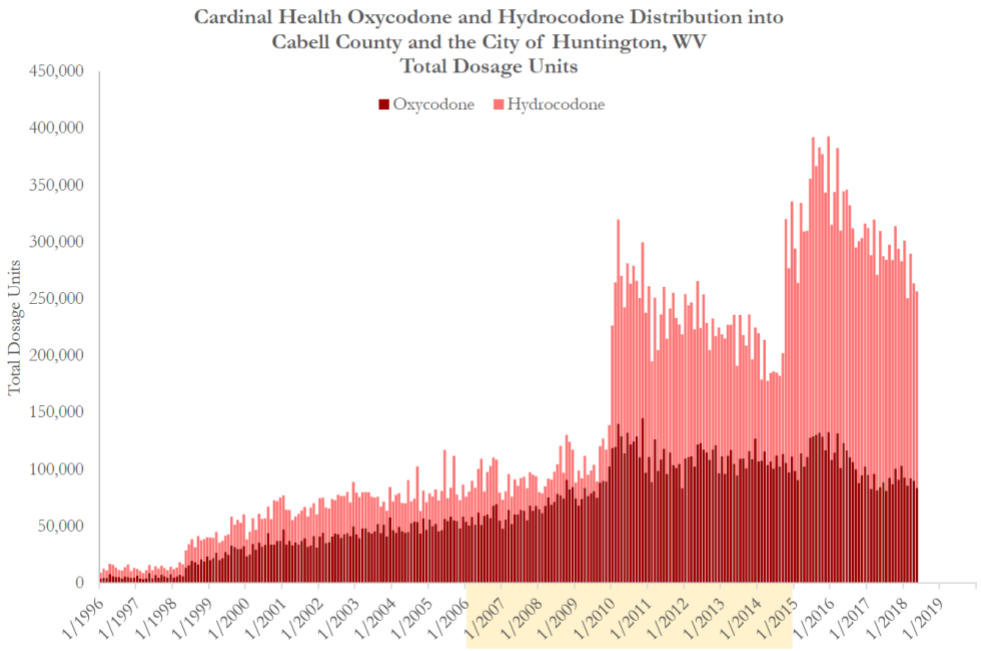


Distribution from Cardinal Health was as follows:[100]

[100] *Id.* at 35-36.

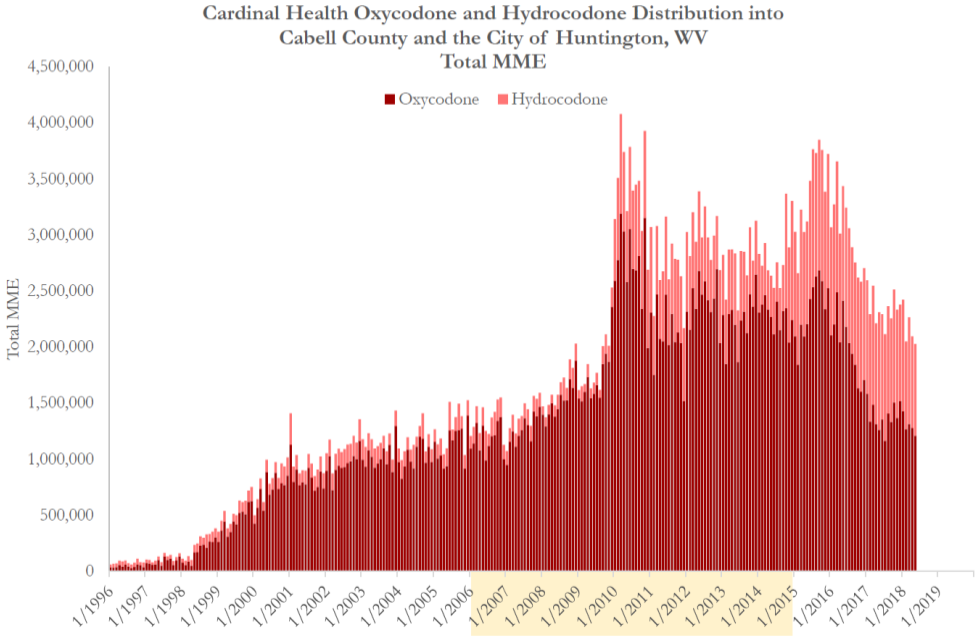
Confidential Subject to Protective Order

Region: Cabell County and the City of Huntington, WV
Time: 1/1996 - 5/2018
Seller: Cardinal Health
Buyer: All Dispensers
Drug: Oxycodone and Hydrocodone



Data source: ARCOS (2006-2014) and Defendant Transactional Data (Cardinal 1/1996-5/2018)

Region: Cabell County and the City of Huntington, WV
Time: 1/1996 - 5/2018
Seller: Cardinal Health
Buyer: All Dispensers
Drug: Oxycodone and Hydrocodone



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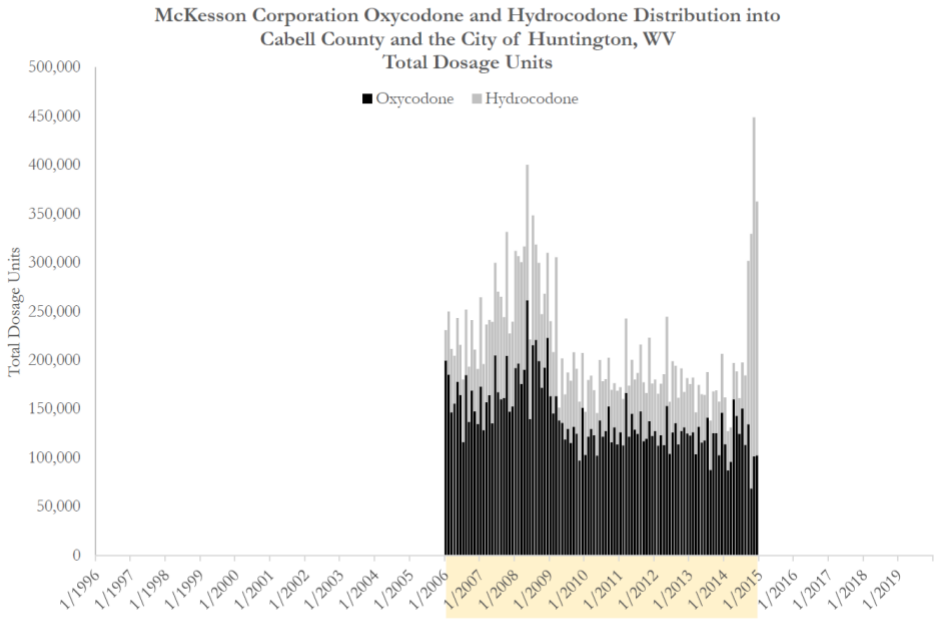
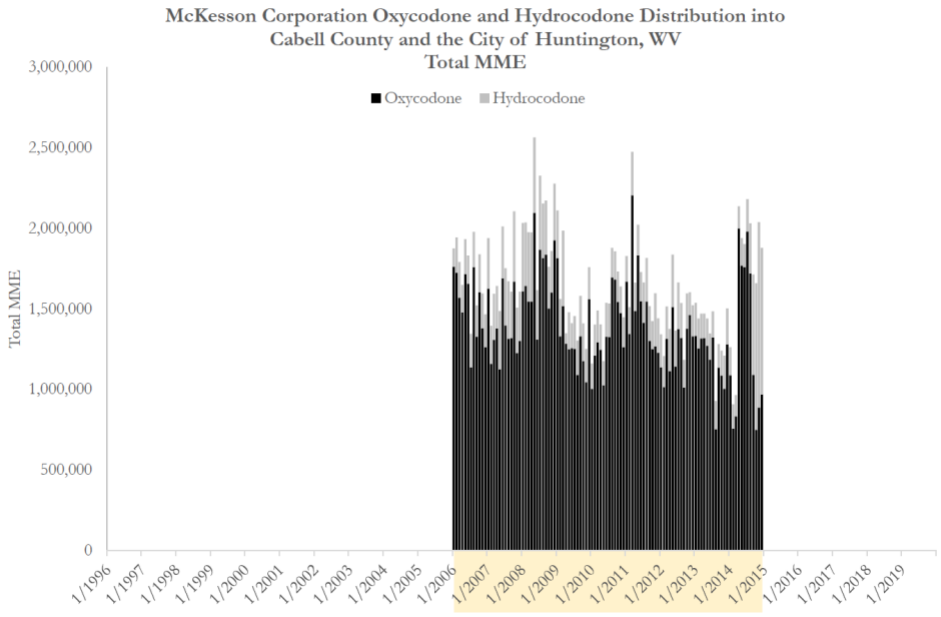
Distribution from McKesson was as follows:[101]

Region: Cabell County and the City of Huntington, WV
Time: 1/2006 - 12/2014
Seller: McKesson Corporation
Buyer: All Dispensers
Drug: Oxycodone and Hydrocodone



Data source: ARCOS (2006-2014)

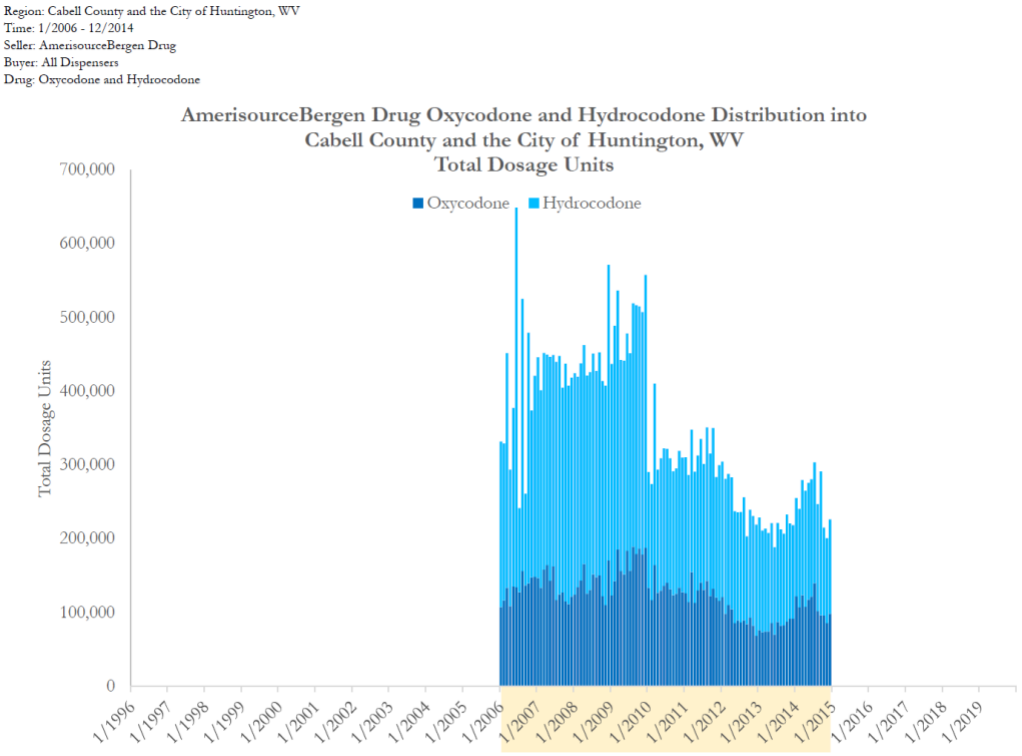
Region: Cabell County and the City of Huntington, WV
Time: 1/2006 - 12/2014
Seller: McKesson Corporation
Buyer: All Dispensers
Drug: Oxycodone and Hydrocodone

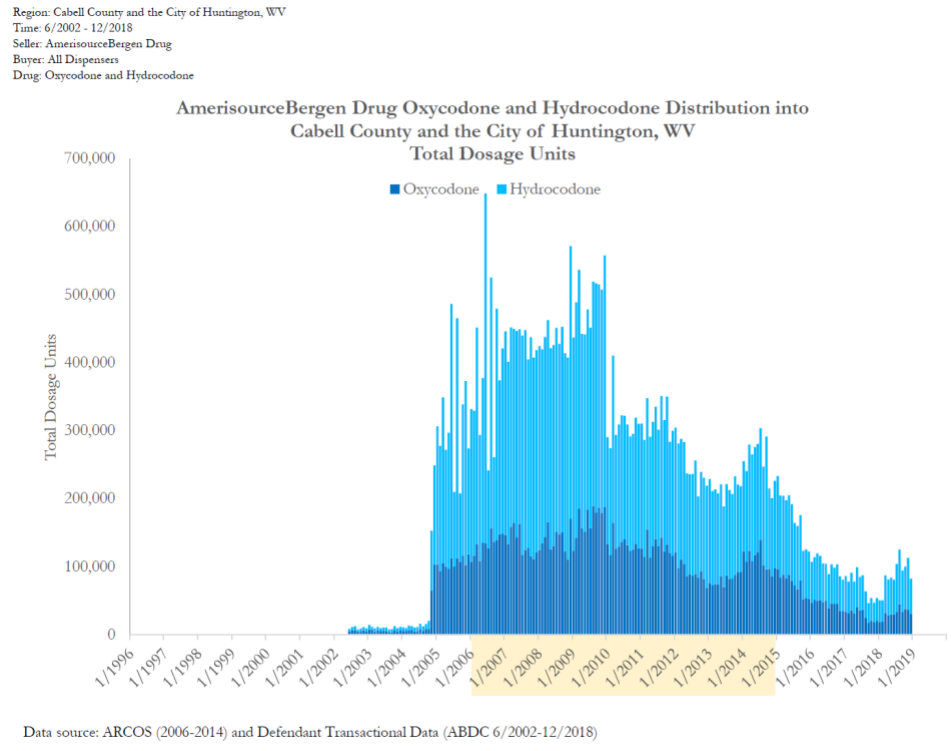


[101] *Id.* at 38-39.

Confidential Subject to Protective Order

Amerisource Bergen's was:[102]





[102] *Id.* at 28-29.

Opioids don't just stop at county or state borders, however. Indeed, as detailed in the Expert Report of James Rafalski, an additional wave of opioids were making their way into West Virginia from Florida and other states via the route often referred to as the "Oxy Express" or "Blue Highway."[103] City and County documents show this influx of Defendants pills into the Cabell Huntington Community.[104] Defendants own documents acknowledge this migration.[105] Internally, Amerisource Bergen even joked about the problem of pill migration from Florida:[106]

The massive exposure of a population to a highly addictive class of drug and the human cost of addiction to families and communities is not something a drug distributor should joke about. In fact, the relationship between opioid supply, death and addiction is starkly illustrated by the CDC:[107]

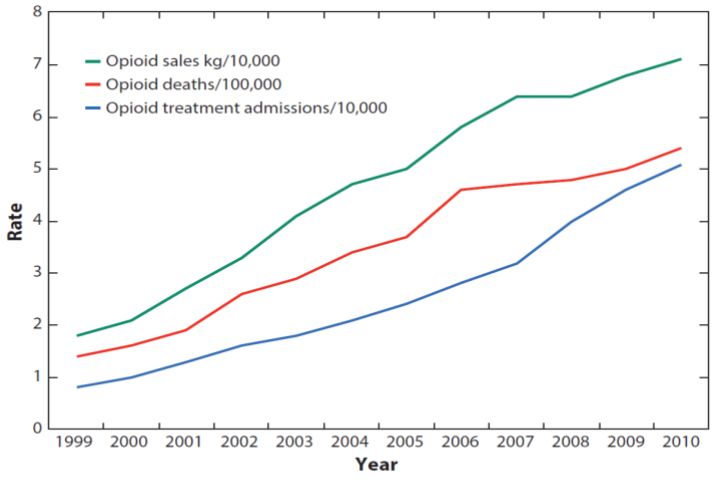


Figure 1

Rates of OPR sales, OPR-related unintentional overdose deaths, and OPR addiction treatment admissions, 1999–2010. Abbreviation: OPR, opioid pain reliever. Source: 10.

[103] Expert Report of James Rafalski at 53.

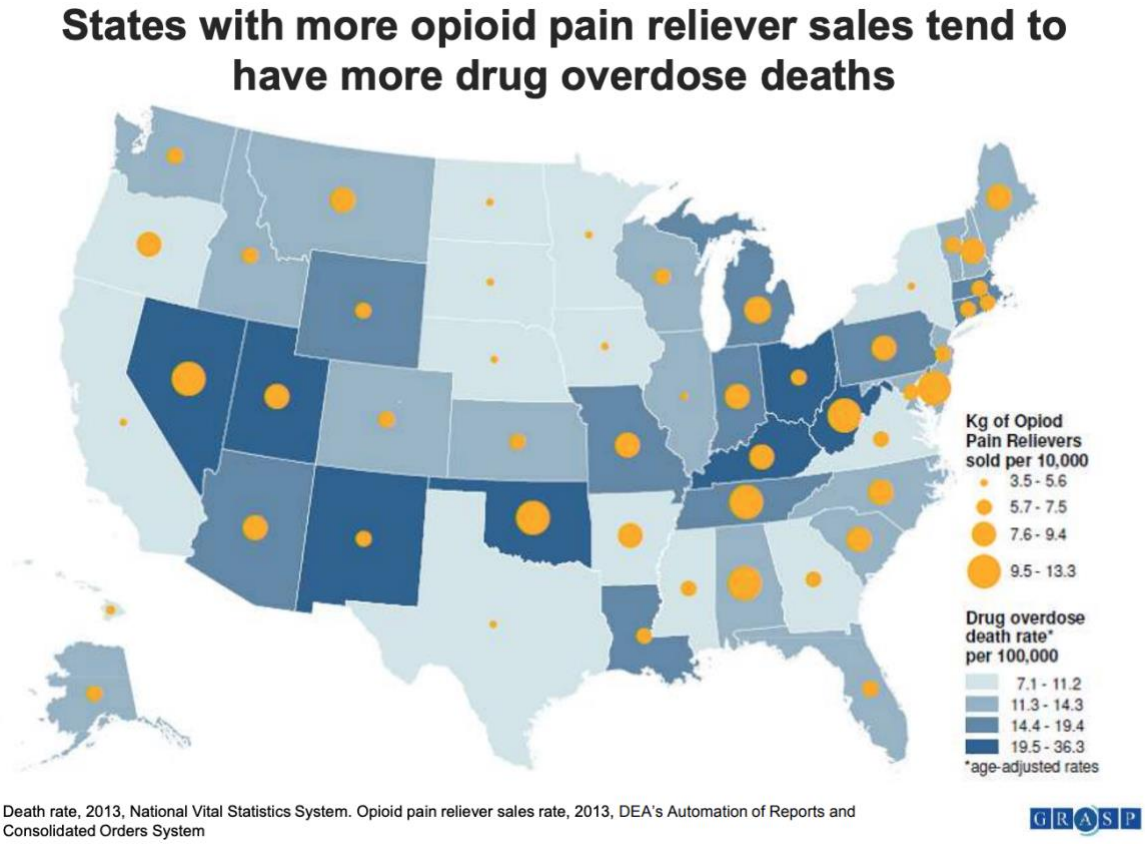
[104] HUNT_00286731; HUNT_00029464; CCDS_0044668 (CCSD Arrest Report); CCDS_0029884; HUNT_00263760 (HPD Arrest Report); CCDS_0028875 (CCSD Arrest Report); CCIRC_0303373, CCIRC_0303340 (Indictment); HUNT_00730154 (BPD Arrest Report).

[105] CAH_ALASKA_00190590 at 597; MCKMDL00407451 at 465; *see also* Edward Hazewski Deposition (October 25, 2018) at 71:8-72:10 (ABDC witness acknowledging pill migration from Florida).

[106] ABDCMDL00569571; ABDCMDL00000124

[107] Centers for Disease Control and Prevention. (2011). Vital signs: overdoses of prescription opioid pain relievers—United States, 1999–2008. *MMWR*, (60), 1487-92; Centers for Disease Control and Prevention. (2013). Vital signs: overdoses of prescription opioid pain relievers—United States, 1999–2010. *MMWR*, (62), 537-42; Centers for Disease Control and Prevention. (2014). QuickStats: rates of drug poisoning deaths involving heroin,* by selected age and racial/ethnic groups—United States, 2002 and 2011. *MMWR*, (63), 595; Defendants' internal documents cite and acknowledge this correlation. *See e.g.* ABDCMDL08307607; MCK-AGMS-006-0000886; MCKMDL00557252 at 261; CAH_MDL2804_01493700.

As opioids flooded into communities across the country, and as they became more available in our homes, opportunities for opioid misuse increased. In 2015, 11.5 million Americans are estimated to have misused prescription opioids. The most commonly reported motivation for misuse (63%) was borrowing pills to relieve physical pain.[108] In states where more opioids were consumed, more people became addicted and more people died.[109] Studies have also found that in counties where the opioid industry spent more money to influence prescribing, more opioids were prescribed, and more people died.[110]



[108] Han B, Compton WM, Blanco C, et al. (2017). Prescription Opioid Use, Misuse, and Use Disorders in U.S. Adults: 2015 National Survey on Drug Use and Health. *Ann Intern Med,* 167(5), 293-301. doi: 10.7326/M17-086

[109] Baldwin, G. Overview of the Public Health Burden of Prescription Drug and Heroin Overdoses. CDC Presentation at FDA meeting. (July 1, 2015). *Available at* https://www.fda.gov/media/93249/download.

[110] Hadland, SE, et al. (2019). Association of Pharmaceutical Industry Marketing of Opioid Products with Mortality From Opioid-Related Overdoses [published correction appears in *JAMA Netw Open*. 2019 Mar 1;2(3):e191625]. *JAMA Netw Open*., 2(1), e186007. doi:10.1001/jamanetworkopen.2018.6007; Hollander MAG, et al. (2019); Association between Opioid Prescribing in Medicare and Pharmaceutical Company Gifts by Physician Specialty [published online ahead of print, 2019 Dec. 2]. *J Gen Intern Med*.doi:10.1007/s11606-019-05470-0

Exposure is particularly harmful when it occurs for long durations and at high doses. Any individual who takes opioids on a daily basis for more than a few days will be at high risk for developing opioid addiction, which is caused by repeated use of opioids. The reason for use, whether medical, recreational or self-medicating, has less influence on the development of addiction than the duration of use. Although the opioid industry has promoted the false notion that only a small subset of the population are at risk for developing opioid addiction from exposure to opioids, health officials have emphasized the message that opioids are inherently addictive – that the problem is "risky drugs, not risky patients."[111] In a medical claims data study of more than 500,000 patients with chronic pain, the single greatest risk factor for development of opioid addiction was duration of use.[112] In a related study using the same data set, about two-thirds of patients who took opioids on a daily basis for 90 days were still taking opioids five years later.[113]

Opioid molecules differ in the amount required to produce an effect of given intensity, also called potency. The morphine milligram equivalent (MME) daily dose for each opioid can be calculated using a conversion factor. UHDU opioids are formulations that when taken as directed exceed 90 MME/day, a dose the Centers for Disease Control and Prevention (CDC) has determined to be dangerously high.[114] UHDU opioids, which include immediate release oxycodone 30mg tablets, are especially dangerous when misused, a practice that is common among adolescents and young adults. In 2015, there were 969,000 youths aged 12 to 17 who misused prescription pain relievers, and 3.0 million young adults aged 18 to 25.[115] An opioid naive adolescent who makes the mistake of experimenting with an UHDU opioid could easily suffer a fatal overdose. Experimentation with a low dosage opioid is also dangerous and can lead to addiction but is less likely to result in life threatening respiratory depression.

Higher opioid dosages are associated with increased overdose risk. CDC's review included four well designed studies that evaluated similar MME/day dose ranges for association with overdose risk.[116] Compared with opioids prescribed at <20 MME/day the odds of overdose among patients prescribed opioids for chronic nonmalignant pain were:

[111] Dowell D, et al. (2013). Opioid Analgesics—Risky Drugs, Not Risky Patients. *JAMA*, 309(21), 2219–2220. doi:10.1001/jama.2013.5794

[113] Martin BC, et al. (2011). Long-term chronic opioid therapy discontinuation rates from the TROUP study. *J Gen Intern Med.*, 26(12), 1450-1457. doi: 10.1007/s11606-011-1771-0

[114] Dowell D, et al. (2016). CDC guideline for prescribing opioids for chronic pain United States, 2016. *JAMA*, 315(15), 1624-1645. doi:10.1001/jama.2016.1464

[115] Hughes, A., et al. Prescription drug use and misuse in the United States: Results from the 2015 National Survey on Drug Use and Health. *NSDUH, available at*, https://www.samhsa.gov/data/sites/default/files/NSDUH-FFR2-2015/NSDUH-FFR2-2015.htm.

[116] Zedler B, et al. (2014). Risk factors for serious prescription opioid-related toxicity or overdose among Veterans Health Administration patients. *Pain Med*, 15(11), 1911–29. doi: 10.1111/pme.12480 Bohnert AS, et al. (2011). Association between opioid prescribing patterns and opioid overdose-related deaths. *JAMA*, 305(13), 1315–21. doi:10.1001/jama.2011.370; Dunn KM, et al. (2010). Opioid prescriptions for chronic pain and overdose: a cohort study. *Ann Intern Med*, 152(2), 85–92. doi:

- 1.3 to 1.9 for dosages of 20 to <50 MME/day
- 1.9 to 4.6 for dosages of 50 to <100 MME/day
- 2.0 to 8.9 for dosages of ≥100 MME/day

Compared with dosages of 1-<20 MME/day, the absolute risk difference approximation was:

- 0.15% for fatal overdose and 1.40% for any overdose at dosages of 50 to <100 MME/day
- 0.25% for fatal overdose and 4.04% for any overdose at dosages of ≥100 MME/day

CDC found that keeping dosages under 50 MME/day reduces overdose risk among a large proportion of patients and that dosages under 50 MME/day are safer than dosages of 50–100 MME/day, and that dosages under 20 MME/day are safer than dosages of 20–50 MME/day. CDC's expert consensus was that increasing dosages to 50 or more MME/day increases overdose risk without necessarily adding benefits for pain control or function.[117]

Dose-related serious harms are not limited to risk of overdose. High dose opioids are associated with increased risk for motor vehicle accidents, fractures from falls, immune suppression, and opioid associated androgen deficiency which can cause reduced libido, erectile dysfunction, fatigue, depression, decreased muscle mass, weight gain, osteoporosis and infertility.[118]

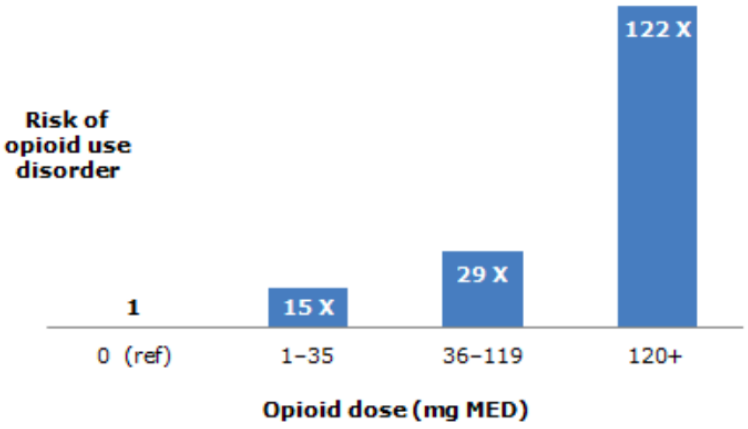
One of the most serious adverse events associated with high dosages is development of an Opioid Use Disorder. A person taking a relatively low dose of prescribed opioids is 15 times as likely to develop an opioid use disorder (OUD) as a person who has not been prescribed opioids. The risk continues to rise as doses increase; at high doses (≥ 120 mg MED) of opioids, the

10.7326/0003-4819-152-2-201001190-00006; Gomes T, et al. (2011). Opioid dose and drug-related mortality in patients with nonmalignant pain. Arch Intern Med, 171(7), 686–91. doi:10.1001/archinternmed.2011.117

[117] Dowell D, et al. (2016). CDC guideline for prescribing opioids for chronic pain—United States, 2016. *JAMA*, 315(15), 1624-1645. doi:10.1001/jama.2016.1464

[118] Saunders KW, et al. (2010). Relationship of opioid use and dosage levels to fractures in older chronic pain patients. *J. Gen. Intern. Med.*, 25(4), 310-5. doi: 10.1007/s11606-009-1218-z; Takkouche B, et al. (2007). Psychotropic medications and the risk of fracture: a meta-analysis. *Drug Saf.* 30(2), 171-84. doi: 10.2165/00002018-200730020-00006; Vuong C, et al. (2010). The effects of opioids and opioid analogs on animal and human endocrine systems. *Endocr. Rev*., 31(1), 98–132. doi: 10.1210/er.2009-0009; Angst MS, Clark JD. (2006). Opioid-induced hyperalgesia: a qualitative systematic review. *Anesthesiology*, 104(3), 570–87. doi: 10.1097/00000542-200603000-00025; Tuteja AK, et al. (2010). Opioid-induced bowel disorders and narcotic bowel syndrome in patients with chronic non-cancer pain. *Neurogastroenterol. Motil*. 22(4), 424-30. doi: 10.1111/j.1365-2982.2009.01458.x; Thomson MW, et al. (2006). Xerostomia and medications among 32-year-olds. *Acta Odontol Scand*., 64(4). 249-54. doi: 10.1080/00016350600633243

person's risk of developing OUD is 122 times that of a person who has not been prescribed opioids.[119]



The sharp increase in overdose deaths involving illicit opioids and methamphetamine are a consequence of the flood of prescription opioids that caused an epidemic of addiction.[120] Indeed, according to the federal government's National Survey on Drug Use and Health (NSDUH), 4 out of 5 current heroin users report that their opioid use began with prescription opioids.[121] Many of these individuals switched to heroin after becoming addicted to prescription because heroin was less expensive and easier to obtain. For example, in a sample of opioid-addicted individuals who switched to heroin, 94% reported doing so because prescription opioids "were far more expensive and harder to obtain."[122]

Despite recent declines in prescription opioid supply, the high prevalence of opioid addiction in West Virginia (caused by overexposing the population to prescription opioids) continues to fuel a public health crisis. As noted in the Expert Report of Kathleen Keyes, Ph.D., even though there have been rapid increases in opioid overdose death due to heroin and synthetic opioids, deaths as a result of prescription opioids overdose deaths still outnumber the recent overdose

[119] Edlund MJ, et al. (2014). The role of opioid prescription in incident opioid abuse and dependence among individuals with chronic noncancer pain: the role of opioid prescription. *Clin J Pain.*, 30(7), 557-64. Doi: 10.1097/AJP.0000000000000021

[120] Muhuri PK, et al. (2013). Associations of nonmedical pain reliever use and initiation of heroin use in the United States. *CBHSQ Data Rev*. Aug.: http://www.samhsa.gov/data/sites/ Default/files/DR006/DR006/nonmedical-pain-reliever-use-2013.htm; MCKMDL00407451; MCKMDL00336347.

[121] Muhuri PK, et al. Associations of nonmedical pain reliever use and initiation of heroin use in the United States.

[122] Cicero TJ, et al. (2014). The changing face of heroin use in the United States: a retrospective analysis of the past 50 years. *JAMA Psychiatry*, 71(7), 821-826. doi:10.1001/jamapsychiatry.2014.366

epidemic as a result of illicit opioids.[123] Indeed, the total number of overdose deaths due to natural and semisynthetic opioids has been greater (175,004) than the recorded deaths from heroin over the same time period (115,568) or the recorded number of deaths due to non-methadone synthetic opioids (124,486).[124] A June 4, 2020 report issued by the West Virginia Attorney General details that prescription opioid-related deaths were the first and primary driver of opioid-related deaths in West Virginia from 2001-2015.[125]

Moreover, the transition to illicit opioids from prescription opioids, especially in the time period since 2014, has been well documented and the connection established in scientific literature.[126]

The rise in methamphetamine use and overdose deaths has also been linked to the Opioid Epidemic. In a study of 13,000 patients receiving addiction treatment, methamphetamine use among people with a primary opioid use disorder doubled from 2011 to 2017. The reasons opioid addicted patients gave for using methamphetamine included a desire to offset the sedation caused by opioids with a stimulant and a desire to enhance the effects of the opioid.[127] Another study based on data from the National Survey on Drug Use and Health found significant increases in past month methamphetamine use among people with a history of heroin use disorder and

[123] Expert Report of Kathleen Keyes at 26-27.

[124] *Id.*

[125] Office of the Attorney General of West Virginia. *DEA's Failure to Combat Diversion Cost Lives: Results from the West Virginia Attorney General's Investigation into the DEA's Catastrophic Failure to Manage the National Drug Quota System from 2010-2016*, June 4, 2020.

[126] Muhuri PK, et al. Associations of nonmedical pain reliever use and initiation of heroin use in the United States.; Cicero TJ, et al. (2014). The changing face of heroin use in the United States: a retrospective analysis of the past 50 years. *JAMA Psychiatry*, 71(7), 821-826. doi:10.1001/jamapsychiatry.2014.366; Compton WM, et al. (2016). Relationship between Nonmedical Prescription-Opioid Use and Heroin Use. *N Engl J Med*., 374, 154-163 at 157doi:10.1056/NEJMra1508490; Lankenau SE, et al (2012). Initiation into prescription opioid misuse amongst young injection drug users. *Int J Drug Policy*, 23(1), 37-44, at 41. doi: 10.1016/j.drugpo.2011.05.014; Compton, *et al.*, "Relationship Between NPOU and Heroin Use," fn. **Error! Bookmark not defined.**, above, at 156.; Muhuri, *et al.*, "Associations of NMPRU and Heroin," above, at 1; Inciardi JA, et al., Prescription Opioid Abuse and Diversion in an Urban Community: The Results of an Ultra-Rapid Assessment. *Pain Medicine*. 10(3), 537-548, at 544. doi: 10.1111/j.1526-4637.2009.00603.x; Mars SG, *et al.*, "Every 'Never' I Said Came True": Transitions from opioid pills to heroin injecting. *Int'l J. of Drug Policy*, 25(2), 257-266, at 264. doi: 10.1016/j.drugpo.2013.10.004

[127] Ellis MS, et al. (2018). Twin epidemics: The surging rise of methamphetamine use in chronic opioid users. *Drug Alcohol Depend*, 193, 14-20. doi: 10.1016/j.drugalcdep.2018.08.029

prescription opioid use disorder.[128] For example, among heroin users, methamphetamine use tripled from 9.0% in 2015 to 30.2% in 2017.[129]

4. Specifically, the following conduct by each of the Defendants was a substantial factor in causing the flood of prescription opioids into the United States, West Virginia and the Huntington-Cabell Community, fell below any reasonable standard of care, and these factors combined synergistically to produce a severely negative impact on the Cabell-Huntington Community public health and safety.

Up until the mid-1990s, the medical community understood that opioid medications were highly addictive and that their clinical role was limited to short-term use and end-of-life care. It was a brilliant, multi-faceted marketing campaign, disguised as education and advocacy, that caused a dramatic change in the culture of prescribing and flood of opioids. The campaign to increase opioid sales included close collaboration from an array of stakeholders including opioid manufacturers, key opinion leaders, patient groups, professional organizations, quasi-governmental organizations and the Defendants. These diverse stakeholders worked as a team, with a common goal of increasing opioid supply. On this team, each group played its part to deceive the medical community, state and federal policymakers, the media and the public. As early as 1996, Purdue recognized the Defendants as key "trade partners," controlling 80% of the drug market."[130] Collaboration was universally recognized by Defendants and opioid manufacturers alike as necessary to achieve the goal of increased sales for all.[131]

Once the opioid industry had dramatically expanded the demand for prescription opioids, they worked together to fuel the demand by shipping a massive supply of prescription opioids into communities around the United States, including in dramatically elevated numbers into West Virginia. Indeed, Defendants flooded the United States with a wave of pills that exposed such a wide swath of the United States population, and acutely the population in West Virginia and the Cabell-Huntington Community, with such an enormous volume of opioids that it was foreseeable that addiction and all the resultant consequences of addiction would follow. Moreover, Defendants failed to maintain adequate systems to ensure that just this type of public health disaster did not occur as a result of the controlled substances they were allowed to sell. Indeed, it became evident time and again that Defendants lacked adequate systems to prevent diversion and protect public health. Defendants and their opioid trade partners were repeatedly cited for

[128] Strickland JC, et al. (2019). A nationally representative analysis of "twin epidemics": Rising rates of methamphetamine use among persons who use opioids. *Drug Alcohol Depend*, 204, 107592. doi: 10.1016/j.drugalcdep.2019.107592

[129] *Id.*

[130] PKY181715440.

[131] *See e.g.* PPLPC004000182848; PPLP004474439-440; CAH_MDL2804_00879572; MCKMDL00536290; MCKMDL00634412.

violating the laws designed to protect communities, yet they kept selling, as internal documents repeatedly described "business as usual."[132]

Diversion became rampant and the Cabell-Huntington Community, and many communities like it across the nation, fell into the throes of an addiction epidemic. Instead of finding ways to remedy the devastation they had caused, Defendants and their opioid industry partners took numerous actions to prevent safety measures that could have protected the public, because those safety measures would have reduced sales. At the same time, Defendants falsely and repeatedly claimed that they were remedying the problem and doing everything they could to prevent diversion and harm. They were not. Even today, Defendants refuse to take responsibility for their actions.

These actions combined to produce the Opioid Epidemic that the Cabell-Huntington Community and the United States is facing today. Specifically, the Defendants conduct that, in my professional opinion, was a substantial factor in causing the Opioid Epidemic can be summarized as follows.

a. The Defendants worked to dramatically expand and then maintain the market, the demand and, therefore, the supply of prescription opioids through participating in a massive marketing and misinformation campaign about the risks and benefits of prescription opioids. [133]

It was long thought that the Defendants had no part in the marketing and misinformation campaign that so dramatically changed the culture of opioid prescribing, the demand for opioids, and ultimately the supply of opioids. Indeed, Defendants have repeatedly issued public denials of their role in expanding demand and outright denied marketing opioid products. For example, AmerisourceBergen stated to the press that Amerisource "does not . . . market these drugs or take any action to create demand for their use."[134] Amerisource Bergen's CEO Steve Collis published an op-ed in 2017 stating "We don't manufacture these drugs, provide them directly to patients or take any action to drive their demand.".[135] McKesson's CEO John Hammergren, even testified to congress that, "[a]s a distributor, McKesson does not manufacture prescription drugs, and we do not market them to doctors or patients. Nor do we market any particular category of drugs, such as opioids, to pharmacies."[136]

[132] *See* repeated references to continuing despite regulations, "business as usual." MCKMDL00354776; MCKMDL00497923 at 926; MCKMDL00535683; MCKMDL00541773; ABDCMDL01610737; ABDCMDL01691017; ABDCMDL07229938; CAH_MDL_PRIORPROD_DEA07_00053986; CAH_MDL_PRIORPROD_DEA07_00509337; CAH_MDL2804_01942269.

[133] I have been provided the Expert Report of Jakki Mohr, Ph.D. Dr. Mohr's Report and the evidence cited therein provide additional basis for the opinions I express in this Section.

[134] *See* ABDCMDL03830512 at 566 (8/24/17 Cincinnati Enquirer op-ed by Gabe Weissman).

[135] ABDCMDL00359830 (9/21/17 Linked In op-ed by CEO Steve Collis).

[136] *See* MCKMDL01387750 (May 8, 2018 written testimony of John Hammergren, McKesson CEO).

These denials are blatantly false. Indeed, each participated in marketing opioids, in driving the demand for opioids and in the massive misinformation campaign designed to improperly drive demand and to block efforts to reduce opioid use. Defendants were inextricably intertwined in the opioid drug maker's marketing and misinformation campaign that drove the dramatic increase in demand for opioids sparking the Opioid Epidemic. Defendants sold services to opioid manufacturers for marketing opioids, including direct promotions, patient education and adherence programs, education for health professionals and advertising to pharmacists. Each provided pricing incentives to drive demand and thus their supply. And each participated in the coordinated campaign by industry groups to grow demand by promoting opioids to health professionals and patients. Indeed, all parts of the supply chain worked together with the common purpose of growing, and then maintaining, demand for prescription opioids; thus increasing supply.

Their efforts combined synergistically to produce a sea change in the demand for prescription opioids, an enormous flood of opioids into communities, a supply that would remain unchecked by Defendants as described in Sections VI(4)(b)-(h) below and a resulting public health crisis.

As described more fully, in Sections VI(4)(b)(e)(6), all who participated in the campaign to increase opioid use, including the Defendants, should have foreseen that creating a sharp increase in opioid consumption and thus, increased supply, of a highly addictive class of drug, would produce the kind of negative and long-lasting impacts on public health and safety that we have seen in the United States, in West Virginia and in the Cabell-Huntington Community today. It was both reckless and irresponsible for Defendants to participate in a campaign that caused overexposure of the population to dangerous and addictive pharmaceutical products.

Documents forming the basis for these opinions are cited in the following sections and are listed on Schedule 3 and 4 to this Report.

Evidence now reveals that Defendants did in fact participate in the opioid industry effort to expand the demand for prescription opioids. Major ways Defendants did this include:

- The Defendants marketed and promoted opioids, working with opioid drug makers to develop a broad array of marketing programs to create demand for opioids and thus, increase supply;

- The Defendants provided pricing incentives to opioid manufacturers, pharmacies and consumers to drive demand and thus, increase supply;

- The Defendants affiliated with pharmaceutical industry front groups, industry-influenced professional organizations and health professionals promoting the use of opioids for chronic pain to drive demand through offering false comfort that opioids could be widely used without negative consequences.

1. Defendants' Marketing Divisions Promoted Opioids

The Defendants each offer, and regularly tout, the broad array of marketing services they offer to drug makers.[137] Indeed, when a drug maker wanted to promote their drugs Defendants utilized its existing infrastructure to market that drug to its trade partners, the retail pharmacies. Opioid makers capitalized on Defendants' marketing infrastructure and existing pharmacy customer base, hiring Defendants to market opioid products through these established channels. Defendants' promoted opioids through core marketing techniques such as email and fax blasts, direct mail promotions, web promotion, banner advertising, home page advertising on Defendants' homepages and even telemarketing [138]

For example, through its proprietary web-based ordering application, Order Express, Cardinal advertised opioid products through home page ads and key search word ads on its ordering platform to reach pharmacists at point of purchase.[139] Amerisource Bergen similarly used its own web ordering platform to advertise opioids, running banner advertising.[140] McKesson ran banner ads for opioids on its "One Stop order site" so that "when pharmacists go online to order any McKesson products, they can see [the opioid maker's] banner and clicking through the link directs them to [the opioid product] info on our website."[141]

[137] *See e.g.* ABDCMDL00320068 (2018 Custom Connect presentation outlining marketing services); ABDCMDL00320057 (2018 price list for marketing services); *See* ENDO-CHI_LIT-00470118; for an overview of the manufacturer programs discussed below. *See* MCKMDL00724395-417 (2016 PowerPoint describing McKesson BrandRx Marketing services for manufacturers); MCKMDL00353316-319 (August 20, 2012 McKesson Manufacturer Marketing proposal prepared for Purdue describing various programs); MCKMDL00353374-379 (January 19, 2012 proposal prepared for Cephalon for Actiq and Fentora); *see also,* MCKMDL001736105 at pp. 64-76 (2/21/2019, Deposition testimony of Lisa Young, former marketing director for McKesson, describing branded programs); Amerisource Bergen Form 10-K (2016); Cardinal Health Form 10-K (2016); McKesson Form 10-K (2016); CAH_MDL2804_00131705 (Cardinal/Manufacturer Marketing Services).

[138] *See* Schedule 3; *see e.g.* ABDCMDL00002831 (sell sheet for Mallinckrodt's generic fentanyl patch provided to Amerisource customers); PPLPC004000256865 (2010 email chain re: Amerisource "fax blast" to customers promoting Purdue's Butrans); PPLPC004000146529 (2008 email where Purdue approved Amerisource direct mail and web promotion of OxyContin); ABDCMDL00002828 (SOW with Depomed for Nucynta banner ad on Amerisource web ordering platform); Cardinal sent email blasts to over a hundred thousand pharmacists for an Opana campaign with Endo. ENDO-CHI_LIT-00294169 (8/1/2013 email re: Opana promotion and co-pay card); ENDO-CHI_LIT-00431191 (7/15/2013 email discussing Opana ER email blast; CAH_MDL2804_00131816 (Cardinal Health Marketing Programs Overview).

[139] CAH_MDL2804_00131816 (Cardinal Health Marketing Programs Overview).

[140] PPLPC004000146529 (2008 email where Purdue approved Amerisource direct mail and web promotion of OxyContin); ABDCMDL00002828 (SOW with Depomed for Nucynta banner ad on Amerisource web ordering platform).

[141] ACTAVIS0620245 (10/25/2011 email re Telemarketing Program).

Utilizing existing lists of current pharmacy customers and health care providers, Defendants disseminated opioid promotional materials and advertising content out to thousands of pharmacies, and health professionals across the country. For example, Cardinal offered a customized program called eConnection where Cardinal promoted opioid makers' products to health professionals including for opioid makers Actavis, Endo, Covidien, Teva, and Purdue.[142] These campaigns were so valuable that Teva once paid Cardinal [redacted] to send just one email communication to approximately 105,000 pharmacists.[143] Cardinal offered to its opioid maker partners a way to advertise through Cardinal's platform, such as using email blasts (eConnection), and offering ads on their web-based ordering platform. Cardinal also promoted opioids to its pharmacy customers through its Retail Business Conference (RBC), which Cardinal promoted as "the industry's largest trade show for independent pharmacies."[144] Cardinal offered RBC as a forum to opioid makers for promoting products to pharmacy customers, including paid sponsorship opportunities for opioid makers.[145]

McKesson similarly had its own internal marketing systems which the company used to market opioids to its established customer base through mail, email and direct product shipment, called RxBulletin (email blasts to pharmacies with direct link to drug makers' website or educational materials), RxMail (mail blast of product marketing material), and RxFocus-Autoship (McKesson promotional service where new product samples were shipped to pharmacy customers).[146]

Cardinal and McKesson even provided telemarketing services to drug makers to sell opioid products to pharmacies.[147] These calls were coordinated with detailing in the same geographic

[142] *See* ACTAVIS0220239 (eConnection proof for Kadian campaign); ACTAVIS0600353 (marketing Proposal prepared for Actavis by Kristine Fidle); ALLERGAN_MDL_00000044 (Actavis Marketing Programs Agreement); ALLERGAN_MDL_00019229 (Kadian Pharmacy Flyer); ENDO-OR-CID-00418114 (re: Endo Dear Pharmacy Letter and Tote Stuffer); EPI000888887 (re: marketing programs for Opana ER; MNK-T1_0000823151 (re: eConnection proof for "Exalgo"); CAH_MDL2804_00132780 (SOW for Vantrela ER); PPLPC004000298375 (eConnection Proofs); CAH_MDL2804_00125969. (11/8/2012 "Sales Connect" alert, an email and web-based publication.); CAH_MDL2804_00132701 (7/18/2016 "Service Flash"); CAH_MDL2804_00133350 (11/21/2013 "Service Flash").

[143] CAH_MDL2804_00132726 (eConnection Marketing Contract Review).

[144] *See* RBC Website; see also, CAH_MDL2804_00115420 (RBC 2015 Sales Playbook)

[145] MNK-T1_0000917000 (Mallinckrodt sponsored luncheon for retail pharmacists).

[146] MCKMDL00353282-83; MCKMDL00353279; MCKMDL00353368-69; MCKMDL00353266-67; MCKMDL00490713-16 at pp. 3-4.

[147] ALLERGAN_MDL_02461021 (10/14/2011 email re Oxymorphone campaign); ACTAVIS0620574 (10/14/2011); see also ACTAVIS0623269 (8/26/2011 email discussing Actavis Oxymorphone Promotional Plan includes McKesson telemarketers calling "500 independent pharmacies with highest script history" to provide incentives).

area so as to maximize the impact on demand from coordinated marketing activities.[148] As acknowledged by opioid maker Actavis' in internal documents, all of these campaigns were designed to "drive awareness and shipment into the pharmacies." [149]

In April, 2013, Cardinal became concerned about blatantly advertising opioids on its website, pulling back on certain types of opioid marketing including key word searching to avoid the appearance that Cardinal Health is "pushing a controlled substance."[150] Cardinal's internal documents discussing this shift admit that "it was never previously been an issue for us to advertise on behalf of a manufacturer" and that pulling back on key word advertising for opioids was "a big change which will affect a lot of our processes."[151] Internal documents show that Cardinal's concern was getting caught overtly marketing opioids, while it went on to promote opioids in other less overt ways, contributing to increased demand and therefore supply.

Likewise, after growing demand for years through marketing and after flooding the market with supply, McKesson falsely claimed to adopt a policy of not marketing opioids. This policy, however, was insincere because the definition of "marketing" contained therein was so exceedingly narrow that it restricted little if any marketing at all.[152] In fact, McKesson continues to sell product ads on its website for the opioids it distributes.[153] For example, in 2016, McKesson contracted with Purdue to advertise Butrans on McKesson's online ordering portal, McKesson Connect.[154] And McKesson continued to market opioids with voucher programs through at least 2018.[155]

Not only do Defendants market opioids, their marketing efforts are effective in driving sales of these products.[156] McKesson's RelayHealth Program showed results that included a 173% new prescription increase for newly launched products, a 27% improvement in patient adherence as a

[148] *Id.*

[149] ACTAVIS0623266 (8/26/2011 email re Oxymorphone Promotion and chargeback results to date).

[150] MNK-T1_0007819281 (4/12/13 email chain between Cardinal and Covidien).

[151] *Id.*

[152] *See* MCKMDL00695128-32.

[153] *See e.g.* https://mms.mckesson.com/catalog?query=oxycontin; s*ee also e.g.* MCKMDL00353277-278 (2016 contract for four weeks of DirectRx Advertising).

[154] *See* MCKMDL00353277-278 (2016 contract for four weeks of DirectRx Advertising).

[155] *See* MCKMDL00385864-869 (April 5, 2018 letter to the *Tennessee* Attorney General describing opioid voucher programs in *Tennessee*).

[156] *See e.g.* PPLPC030000564197; PPLP025000149099; MCK-AGMS-069-00091; MCKMDL00724422; MNK-T1 0000416504.

result of McKesson's efforts and a 90% sustained lift after 12 months.[157] As McKesson touts, its programs create "a flexible, efficient engine to maximize investment in core marketing tactics."[158] McKesson similarly tracked the effectiveness of its marketing programs for its opioid manufacturer customers.. For example, in August 2016, McKesson ran an ad for Purdue's Oxycontin Reformulation for one week. According to McKesson, units sold went from 15,000 to 22,483 in one week.[159] Additionally, McKesson analyzed its evoucher program, noting its success in switching patients from competitors to Oxycontin, getting patients to fill second prescriptions of Oxycontin sooner and physician prescribing leading to sales lift.[160]

2. Defendants drove demand through deceptive educational programs for health professionals.

The opioid industry's campaign to increase demand had as a critical element convincing the medical community that opioids could be used widely without risk. We have long known of Purdue and other opioid makers' efforts in disguising marketing as physician "education" to widely spread misinformation about the safety and effectiveness of long-term opioid use. Opioid makers like Purdue Pharma, Endo, Janssen, Allergan and Teva sponsored a massive marketing effort designed to change demand through sponsoring continuing medical education ("CME") conferences and paying key opinion leaders to promote widespread use of opioids.[161] What we didn't know until recently, was that Defendants participated in this "educational" campaign designed to inappropriately increase demand for opioids. In fact, each Defendant had an educational arm (Amerisource Bergen bought and ran a separate company) that provided "education" to doctors, pharmacists and healthcare providers regarding the drugs each was selling.

From 2004 to 2015, Amerisource Bergen owned a Continuing Medical Education ("CME") company, Imedex.[162] Imedex produced numerous CME courses for doctors, and received fees

[157] PPLPC030000564197.

[158] *Id.*

[159] *See* MCKMDL00353307 (Direct Rx Advertising Program Results); *See* also JAN-MS-01071368-425 (presentation discussing the effectiveness of McKesson's marketing of Nucynta).

[160] PPLPC025000149099.

[161] *See e.g.* AAFP0001084 (2/24/2016 Sponsorship Letter of Agreement between Teva and American Academy of Family Physicians); AAPA_00000594 (2014 Grant Transaction Recap); ENDO-OPIOID_MDL-02821120 (Continuing Medical Education Contributor Disclosure and Contract); PPLPC029000236513 (Marketing Education Programs – Concept Proposal.) *See also,* Van Zee, A. (2009). The promotion and marketing of OxyContin: Commercial triumph, public health tragedy. *Am J of Public Health*, 99(2), 221-227. doi: 10.2105/AJPH.2007.131714

[162] AmerisourceBergen purchased Imedex on May 4, 2010, and the "equity and enterprise" price was $16 million. Imedex had calendar 2003 revenues of approximately $11 million, *available at,* https://investor.amerisourcebergen.com/news/news-details/2004/AmerisourceBergen-Acquires-Imedex-

and grants from pharmaceutical companies for CME's that involved pain management and opioids.[163] As early as 2000, Imedex had been involved in Purdue's massive misinformation campaign to change the medical community's view of opioids, hosting the 2000 a pain conference organized by Dr. Russell Portenoy, one the opioid industry's most prominent KOLs.[164]

In 2002, in a blatant violation of the Accreditation Council for Continuing Medical Education rules prohibiting pharmaceutical companies from influencing the content of educational programs, Imedex allowed Endo to edit a CME program and add content about extended-release oxymorphone.[165] In so doing, Imedex helped Endo prepare for the launch of Opana, a new extended-release oxymorphone product.

Amerisource Bergen went to great lengths to hide the influence of pharmaceutical industry money on the CME programs Imedex was running. AmerisourceBergen's Marketing Code of Conduct even exempts Imedex is from its ethical guidelines.[166] And, through Imedex, Amerisource Bergen, lobbied against transparency and disclosure of indirect payments from pharmaceutical manufacturers to physician faculty of CME programs.[167]

Amerisource Bergen also bought and ran an entity that helped expand demand for opioids through scientific misinformation. That entity, called Xcenda was acquired by AmerisourceBergen in 2007 for $25 million.[168] Xcenda became part of AmerisourceBergen's Specialty Group, "enhancing the Company's existing manufacturer services businesses and providing additional capabilities in the key areas of pharmaceutical brand services, applied

Inc-AmerisourceBergen-Adds-Accredited-Physician-Education-Services/default.aspx, *See also* CAH_MDL2804_03177666.

[163] TEVA_MDL_A_06771229 (2009 grant agreement with Cephalon in which information regarding the opioids Actiq and Fentora is presented for possible discussion); PKY180796628 (Purdue funded Imedex for 2000 Pain and Chemical Dependency conference with Russell Portenoy to discuss interface between pain management and chemical dependency and under treatment of pain).

[164] PKY180796623 (Imedex Letter of Agreement); PKY180796628 (Pain Management and Chemical Dependency, Conference Agenda).

[165] ENDO-OPIOID_MDL-02261219

[166] ABDC-WVFED00018369 (2009 AmerisourceBergen Marketing Code of Conduct).

[167] Comments to proposed regulations issued under 42 CFR 402 and 403 (mandated by Section 6002 of the Patient Protection and Affordable Care Act), at p. 10, *available at,* https://policymed.typepad.com/files/imedex-comments-to-cms-ppsa.pdf (there are a number of provisions … which unduly insert accredited CME providers and the faculty of their activities, who may be covered recipients under the Act, into a reporting and accountability responsibility that are not included in the Act itself but represent an attempt by CMS and HHS to broaden the reporting requirements.").

[168] *AmerisourceBergen to acquire Xcenda LLC.* Reuters (April 3, 2007), *available at,* https://www.reuters.com/article/idUSIN20070403082428ABC20070403.

health outcomes and biopharma strategies."[169] AmerisourceBergen represented in its marketing materials that Xcenda has over 20 years of experience "collaborating with pharmaceutical manufacturers … to help them successfully commercialize innovative medical treatments and technologies."[170]

A specific example of Xcenda's partnerships with opioid manufacturers is reflected in its relationship with Teva. After AmerisourceBergen's acquisition of Xcenda, Xcenda's consulting and marketing division received payments from Teva to co-author medical journal articles, that promoted long-term use of extended-release opioids.[171] The misleading results were then quoted in marketing materials, speaker presentations, and other public representations about opioids.[172]

For Janssen's launch of the opioid Nucynta, Xcenda developed the "Opioiphobia Speaker Initiative" communicating the deceptive and dangerous notion that fear of addiction to opioids is irrational.[173]

Like AmerisourceBergen, Cardinal offers a broad array of online and live continuing education courses for health professionals.[174] Through its Retail Business Conference where it gathers thousands of pharmacists and other healthcare providers each year

Similarly, McKesson's Health Mart administered continuing education courses called Town Halls and Health Mart University.[175] Many of McKesson's Town Hall courses focused on training pharmacies to drive and maximize revenue through selling more product.[176]

[169] *AmerisourceBergen (ABC) Acquires Xcenda LLC for $25M*, Street Insider (April 3, 2007), *available at* https://www.streetinsider.com/Mergers+and+Acquisitions/AmerisourceBergen+%28ABC%29+Acquires+Xcenda+LLC+for+%2425M/1965781.html

[170] ABDCMDL00323380 at p. 41 (profile of Xcenda subsidiary in AmerisourceBergen marketing materials).

[171] TEVA_MDL_A_08855370 (study by Xcenda's Anna D. Coutinho and others, funded by Teva, finding "low observed incidence of opioid abuse" among patients with chronic non-cancer pain who are claimed to be at risk for abuse based on medical and prescription claims data.); Landsman-Blumberg PB, et al. (2017). Health care resource use and cost differences by opioid therapy type among chronic noncancer pain patients. *J Pain Res*, 10,1713-1722. doi: 10.2147/JPR.S130913

[172] *See, e.g.* TEVA_MDL_A_03010773 (Teva abstract of Coutinho/Xcenda findings for 2016 PainWeek).

[173] JAN-MS-00326339.

[174] https://www.cardinalhealth.com/en/medical-affairs/continuing-education-opportunities.html.

[175] MCKMDL00464066 at 13 (PowerPoint discussing the success of 80+ nationwide Town Halls in FY2017); MCKMDL00473378 at 20-21 (PowerPoint on "The McKesson Difference."); MCKMDL00484449.

[176] MCKMDL00474152 at 3 (FY18 Town Hall update presentation discusses seminar entitled "Revenue Remedies").

Not only does McKesson drive demand through "education," but between 2004 and 2020 it owned a technology designed to specifically drive physician decision making.[177] Through its InterQual division, McKesson provided healthcare plans and care providers with "streamlined care management processes" and "appropriateness of care" criteria for "decision support."[178] While InterQual's proprietary content is not publicly available, public and private healthcare plans (payers) cite to InterQual in their coverage policies and standards, showing a heavy reliance on InterQual for decisions on when to cover or authorize treatment.[179] This includes standards and approved clinical pathways for treatment of chronic pain. For example, when Molina Healthcare created a general policy allowing for surgically implanted pain pumps (for the administration of opioids), it relied, in part, on InterQual standards. Specifically, in discussing treatment recommendations, coverage exclusions, and the definition of chronic pain, Molina cited to:

> McKesson InterQual CP Procedures. Epidural Catheter Placement. 2015.
> Clinical Evidence Summary:
> - Chronic Pain Syndrome. 2017.
> - McKesson InterQual Clinical Evidence Summary. Chronic Cancer Pain. 2017[180]

Additional examples include AmeriHealth Caritas, which cited to InterQual standards and definitions in its policies covering pain pumps and spinal stimulators.[181] And MedStar Family Choice, which relied upon InterQual criteria for its administrative policy and procedure for pain management injections, including when injections are indicated.[182]

[177] https://www.businesswire.com/news/home/20040408_240994388_legacyID/en/McKessons-Newest-InterQual-Release-Advances-Care-Management; *See* https://www.mckesson.com/About-McKesson/Newsroom/Press-Releases/2020/McKesson-Completes-Split-Off-Interest-Change-Healthcare/; https://www.changehealthcare.com/solutions/clinical-decision-support/interqual (showing Change's current operation of Interqual).

[178] *See* McKesson Health Solutions. *InterQual Connect™ Enable automation of authorizations requiring medical review, within your existing workflow. available at,* http://www.mckesson.com/documents/providers/interqual-connect-fact-sheet/.

[179] *See, e.g.* https://providers.amerigroup.com/Documents/KSKS_CAID_UMGuidelines.pdf; https://mediproviders.anthem.com/Documents/KYKY_CAID_MP_CUMG_Jan2018.pdf.

[180] https://www.molinahealthcare.com/providers/wa/medicaid/resource/PDF/implanted-intrathecalpain-mcp160.pdf.

[181] https://www.amerihealthcaritasnh.com/global/assets/pdf/provider/clinical-policies/ccp1093-2002-intrathecal-opioid-therapy-chronic-pain.pdf; https://www.amerihealthcaritasla.com/global/assets/pdf/provider/clinical-policies/ccp1098-2004-spinal-cord-stimulators-chronic-pain.pdf.

[182] https://ct1.medstarhealth.org/content/uploads/sites/43/2017/06/Pain-Management-Injections-07-17.pdf

3. Defendants drove demand through patient education and "adherence" programs

Each of the Defendants also drove demand through influencing patient behavior, including corporate programs to ensure opioid users "adhered" to taking their opioid medication and that patients had "access" to opioids. Although opioids should be prescribed for the shortest duration possible, the goal of these efforts was to promote long-term use and dependence on opioids.

AmerisourceBergen drove patient demand in this way through its subsidiary entity, Lash Group, that contracted with opioid manufacturers to promote opioid products through programs for patient medication "adherence" and "patient access."[183] In 2016, for example, Lash contracted with Purdue Pharma to promote and "facilitate access" to the opioid Hysingla, by establishing a call center that served as the "main point of contact for all inquiries, service requests and outbound calls related to the Product.[184] A primary goal of Lash's programs was to increase sales of pharmaceutical products, including opioids.

Cardinal likewise offers comprehensive patient adherence services through its Sonexus "Access & Patient Support" program, promising "compliance and persistency" when "patients don't take their medications as directed."[185] This includes placing outbound calls to patients, as well as answering questions and providing other support.

In addition to its branded marketing programs, McKesson also offers a manufacturer-sponsored Pharmacy Intervention Program ("PIP"), which trains pharmacists on how to provide "coaching sessions" to patients. Identified as "a patient adherence program from the McKesson Sponsored Clinical Services Network," McKesson marketed PIP as a means for to driving sales for both the manufacturer and the pharmacy (and of course- McKesson).[186] To encourage pharmacies to participate, McKesson paid the pharmacy for each completed intervention claim, which was reimbursed by the manufacturer.[187] McKesson not only trained pharmacists to increase opioid sales, it also conducted "behavioral call campaigns" directly to patients. McKesson's call center

[183] *See e.g.* ABDCMDL00323380 at 410 (Amerisource business summary of Lash Group's patient adherence services); TEVA_MDL_A_11786072 (proposal to Teva promises to "enhance the success of pharmaceutical brands by . . . driving adherence").

[184] PPLPC031001481881 (SOW for "ER Coverage and Access Support Program," for which Purdue paid fees to Lash approaching $2.8M per year).

[185] *See* "Patient Adherence Solutions." Cardinal Website, *available at*, https://www.cardinalhealth.com/en/services/manufacturer/biopharmaceutical/patient-access-and-adherence/patient-adherence-solutions.html.

[186] *See* PPLP003299959-63 (PIP Coaching Guide: Butrans); MCKMDL00496195-96 (2010 email describing the PIP program); PPLP003337352 (letter to pharmacists describing PIP program offered in conjunction with Purdue and enclosing patient savings cards and coaching guide for "adherence coaching session[s]"); MCKMDL00493101-04 (email encouraging sales team to stress the importance of adherence coaching sessions to allow McKesson to "show our sponsors an ROI…").

[187] *See* PPLPC022000653078 (Sept. 11, 2013 email re: payment structure for Butrans PIP).

staff, trained in behavioral coaching techniques, would contact patients directly by telephone to ensure that patients took their medications, including opioid products. McKesson claimed its program "takes adherence to a new level through combined behavioral expertise, call center resources, and measurement."[188]

To promote its behavioral marketing programs to manufacturers, McKesson studied the impact of its coaching services on the length of time patients took specific drugs. In 2012, McKesson boasted that behavioral counseling at the pharmacy counter increased prescription fills by 44%.[189] And in 2013, McKesson said pain management patients who received behavioral coaching showed an average of 1.6 incremental fills.[190]

4. Defendants drove demand through financial incentives

The Defendants' contracts with manufacturers provided strong financial incentives to sell as many opioids as possible, placing sales over safety in their contractual incentives. Defendants also benefitted from rebates or "chargebacks" that increased as the sales of pharmaceuticals increased.[191] Joined by this powerful mutual incentive to sell as many opioids as possible, the Defendants and opioid manufacturers cooperated to increase opioid sales.

Cardinal fiercely protected its rebates, even for the most abused opioids. When Mallinckrodt removed larger doses of oxycodone (15mg and 30mg) from its VIP rebate program, due to the DEA viewing "these programs as driving the wrong type of behavior," Cardinal resisted, demanding the rebates for large amounts of orders submitted under the old VIP program.[192]

[188] JAN-MS-01071368-425 at pp. 56-60 (description of behavioral call campaign for Nucynta); PPLPC028000587023 (2014 McKesson proposal for adherence marketing strategies for Hysingla); MCKMDL00726854-884 (2017 proposal for PIP and behavioral call campaigns to Allergan).

[189] JAN-MS-01071368-425 at p. 53 (Nucynta Program Data Review, including training for pharmacists to "evoke patient desires and commitment").

[190] PPLPC002000140782-83 (Butrans PIP objective); PPLPC004000248015-032 (PIP program overview for Butrans).

[191] *See*, e.g., MNK-T1_0000499880 (2011 rebate agreement with AmerisourceBergen in which Mallinckrodt pledged to pay rebates of 13-18 percent based on a sales range of $80M-$150+M in sales of generics); MNK-T1_0000499742 (email to Amerisource where Mallinckrodt indicates that for 2010, ABC is on pace to sell $75M + in generics with an estimated rebate of 15% or $10.6M); MNK-T1_0005981734 (Cardinal agreement with Mallinckrodt including chargeback provisions); MNK-T1_0006684264 (2007 McKesson agreement with Mallinckrodt for volume rebates as high as 20%); MNK-T1_0000443779 (Mallinckrodt annual generic sales figures for FY2010 and FY2011 demonstrating it was paying $600M - $700M per year in chargebacks to distributors); ACTAVIS0623268 (8/19/2011 spreadsheet demonstrates Actavis paid chargebacks to ABC, Cardinal, McKesson, Walmart and several others for oxymorphone).

[192] MNK-T1_0002678103 (email chain dated 10/23/12 between Mallinckrodt and Cardinal).

Additionally, Cardinal ran a corporate program, RX Deals, which facilitated incentives and rebates offered by opioid makers to pharmacy customers for stocking the opioid makers' products.[193]

Additionally, Defendants administered patient voucher and savings programs (such as LoyaltyScript, TrialScript, and eVoucher Rx) designed to drive demand by offering free and discounted opioid products to patients.[194] These voucher and savings programs included free trial offers, savings cards, e-coupons, and manufacturer discounts.[195] For example, McKesson administered voucher programs for Butrans, Hysingla, OxyContin, Ultram ER, Duragesic, Nucynta ER.

5. Defendants drove demand through industry groups who promoted misinformation

As discussed in Section VI(2), above, Defendants drove demand through industry groups that promoted misinformation. In 2001, Dr. Kathleen Foley, a "Key Opinion Leader" ('KOL") funded by opioid makers outlined the necessity for the opioid industry to work in a coordinated manner, behind the veil of industry associations, suggesting to Purdue's Richard Sackler that industry needed to band together to be successful and defeat the bad press that could derail all of their efforts:

> **I'm thinking of an alternative strategy of bringing together all of the members of the pharmaceutical industry**, who have analgesic drugs out there and try **to come together as a sort of cohesive voice** recognizing that your particular drug has been recently identified in the newspapers as a drug issue. I think that there is a tightrope that you need to walk, because **you are a drug company and it would be much better if the advocacy came from outside of the drug company and even better without much in the way of support from you**. So along those lines, the kinds of things that I am thinking of is that maybe **we should call a meeting, bring together representatives from all of**

[193] *See* CAH_MDL_PRIORPROD_DEA07_00854208; CAH_MDL2804_02955355 (ConZip™); CAH_MDL2804_02956235 (Opana ER RxDeal); CAH_MDL2804_02956566 (Nucynta); CAH_MDL2804_02957391 (Stagesic).

[194] MCKMDL00385864-69 (April 5, 2018 letter to the Tennessee AG describing opioid voucher programs in Tennessee); MCKMDL00724422-438 (2016 PowerPoint on McKesson's RelayHealth programs, such as eVoucherRx copay assistance, to help brands capture more filled prescriptions and expand market share); *see also* MNK-T1_0000115216 (1/28/2014 Relay Health presentation to Mallinckrodt, promoting eVoucherRx program to reduce patient abandonment of Xartemis, by increasing copay savings and simplifying process for patients). ; MCKMDL00334317 ("Making Connections Pain Management Program" for Duragesic. Pharmacists submit patient voucher for 25 free patches to McKesson); MCKMDL00334324 (Butrans trial offer "Powered by McKesson"); MCKMDL00334328 (Hysingla ER Savings Card) (Poor copy and Bates number partially obscured).

[195] *Id.*

> **the companies, ideally high level representatives, like presidents or major leaders and strategize about the way to play the media issues.**[196]

The opioid industry's coordination to misinform policymakers, the medical community and the public was carried out mainly through the Pain Care Forum ("PCF"), a group led by Purdue's Chief Washington lobbyist, with active participation from the Healthcare Distribution Alliance ("HDA"), and the National Association of Chain Drug Stores ("NACDS").[197] PCF's membership included companies and trade associations involved in the opium importers, opioid manufacturers, opioid wholesalers, opioid distributers, opioid retailers, front groups and other opioid industry-funded organizations. Together, they worked in a coordinated effort to increase demand for opioids and to block efforts that could result in reduced consumption of opioids. For example, through PCF, numerous groups who fronted a pro-opioid message including the AAPM, APS and APF, the Federation of State Medical Boards ("FSMB"), and an opioid manufacturer trade organization Pharmaceutical Research and Manufacturers Association ("PhRMA") met regularly with HDA, the Defendants' trade association, to coordinate efforts.[198]

In addition to working with opioid manufacturers through PCF, opioid manufacturers were also members of HDA, and AmerisourceBergen, Cardinal Health and McKesson each participate on the HDA's executive committee.[199] In fact, HDA's bylaws vest the Board of Directors' power and authority in the Executive Committee.[200] Both manufacturers and distributors are members of, provide funding for, and have driven the "mission and priorities" of the HDMA/HDA.[201]

[196] PPLPC037000008901

[197] Burt Rosen Deposition (January 16, 2019) at 59:23-60:13; Exh. 1, PPLP004272094 at 96 (List of "Pain Care Forum Participating Organizations" includes manufacturer defendants Allergan, Teva (Cephalon), Mallinckrodt (Covidien), Endo, Johnson & Johnson, and Purdue Pharma; the Healthcare Distribution Management Association (HDA) and National Association of Chain Drug Stores (NACDS) and front groups such as the American Pain Society, American Academy of Pain Medicine, American Association for Pain Medicine, American Pain Foundation, Pain & Policy Studies Group, and Federation of State Medical Boards).

[198] *Id.*

[199] Patrick Kelly [HDA] Deposition (May 10, 2019) at 36:19-37:1; Exh. 448, Rita Norton [AmerisourceBergen]Deposition (01/09/19) at 59:11-60:4; Perry Fri [HDA] Deposition (May 7, 2019) at 68:10-17.

[200] John Gray [HDA] Deposition (July 31, 2020) at 26:16-30:11 (HDA's Board of Directors meets about two-times each year, at all other times, the Boards authority to make decisions is trusted to the Executive Committee, which is led by the Defendants).

[201] Gray Deposition at 21:1-9.

Similarly, the Defendants collaborated with chain drug stores to protect their stake in the opioid supply by participating as board members on key committees for the National Association of Chain Drug Stores ("NACDS"), the trade association for pharmaceutical retailers.[202]

These groups also coordinated their misinformation campaign through PR outfits, whose specialty was crisis management.[203]

As confirmed by the HDA's witness, Mr. Gray, "the strength of a trade association . . . is that they are able to say the things [distributors] can't and won't."[204]

b. Defendants supplied the improperly inflated market with such a large amount of dangerous opioid narcotics that abuse, addiction, misuse and diversion of pills was not only foreseeable, but inevitable[205]

The supply of opioids into the Cabell-Huntington Community is staggering by any measure. Between 2005 and 2014, Defendants sent billions of MMEs into the Cabell Huntington Community of 99,946 people. In fact, between 2006 and 2014, dispensers in the Cabell-Huntington Community received 127.9 million Dosage Units or 3.3 billion MME , enough opioids for every resident in Cabell County and the City of Huntington, WV to consume 142 Dosage Units or 3,650 MME every year from 2006 to 2014.[206] The wave of pills sent into the Cabell-Huntington Community is illustrated in Dr. McCann's Appendix 9, included above.

[202] *See* https://www.nacds.org/membership/directories/associate-companies/; https://www.drugstorenews.com/pharmacy/nacds-elects-board-directors/ (representatives of McKesson and Cardinal Health elected to NACDS Board of Directors in 2009); https://www.supermarketnews.com/executivechanges/wakefern-s-chris-lane-named-nacds-chairman (representatives of McKesson and Cardinal Health elected to NACDS Board of Directors in 2019) (board of director membership is a three year term); CVS-MDLT1-000121577; CVS-MDLT1-000102930; CAH_MDL2804_00886155; CAH_MDL2804_00861971.

[203] https://www.propublica.org/article/inside-purdue-pharma-media-playbook-how-it-planted-the-opioid-anti-story; HDA_MDL_000159563; MCKMDL00719205; HDA_MDL_000202605; HDA_MDL_000159557; ABDCMDL00288484; ABDCMDL00269293; ABDCMDL00269301; ABDCMDL03829334; ABDCMDL03830243; CAH_MDL2804_00112004; ABDCMDL00375084; ENDO-OPIOID_MDL-01623042; ENDO-OPIOID_MDL-02217039; CHI_000272862; PPLPC029000177585; PPLPC031000385886; PKY183402315; JAN-MS-04241287.

[204] Gray Deposition at 40:17-23. *See also*, Gray Deposition Ex. 52 (1/26/2018 email from G. Weissman (ABDC-WVFED00177109)).

[205] In forming my opinions in this Section I have reviewed the Expert Report of Craig McCann, Ph.D., CFA and the Expert Report of James Rafalski. I base my opinions in this section in part on those Reports and the data and sources cited therein. Additional basis for my opinions are cited and discussed herein.

[206] McCann Report at ¶ 17.

The vast majority of opioids sent into West Virginia and Cabell-Huntington Community were oxycodone or hydrocodone.[207] According to Dr. McCann's report, oxycodone and hydrocodone accounted for 85.9% of all dosage units in the transactions in Cabell County and Huntington City, West Virginia from 2006 to 2014.[208] Defendants supplied 57.51% of all of these dosage units[209] and 81.17% of the MMEs of oxycodone and hydrocodone that were shipped into Cabell-Huntington pharmacies.[210]

Defendants' massive supply of opioids into West Virginia, and the resultant public health epidemic, caught the attention of the United States Congress, whose Energy and Commerce Committee launched an investigation into Defendants' practices in West Virginia. What the Committee found, detailed in their 2018 Report, *Red Flags and Warning Signs Ignored: Opioid Distribution and Enforcement Concerns in West Virginia*, the United States House of Representatives was that Defendants were supplying opioids into West Virginia in amounts that, in the Committee's words, "shocked the conscience," including:

- Over 10 years, 20.8 million opioids were shipped to pharmacies in the town of Williamson, home to approximately 3,000 people.

- Another nearly 9 million opioids were distributed in just two years to a single pharmacy in Kermit, West Virginia, population 406.

- Between 2007 and 2012, drug distributors shipped more than 780 million hydrocodone and oxycodone pills to West Virginia.

The Committee noted that each of the Defendants were pouring pills in the West Virginia. Specifically, the report found that between 2005 and 2016:[211]

- Cardinal Health distributed more than 366 million doses of hydrocodone and oxycodone to West Virginia pharmacies.

- McKesson supplied 299.87 million doses of hydrocodone and oxycodone to West Virginia pharmacies.

- AmerisourceBergen distributed 248.16 million doses of hydrocodone and oxycodone to West Virginia pharmacies.

[207] Expert Report of Craig McCann, Appendix 6a at 7, 25-27.

[208] McCann Report at Appendix 6a at 7.

[209] *Id.* Appendix 9 at 734.

[210] *Id.* at Appendix 9 at 748.

[211] Congressional Report at 6.

Between 2006 and 2014 numerous pharmacies in Cabell County each received millions of opioid pills and tens of millions of MMEs (over 115 million in the case of SafeScript Pharmacy No. 6):[212]

Region: Cabell County and the City of Huntington, WV
Time: 2006 - 2014
Seller: All Sellers
Buyer: Retail and Chain Pharmacies
Drug: Oxycodone and Hydrocodone

Oxycodone and Hydrocodone Shipments to Pharmacies in Cabell County and the City of Huntington, WV
2006 - 2014

Page	DEA Number	Pharmacy	Address	Type[1]	Total Dosage Units	Weight in mg	Total MME
1	BS8246349	SafeScript Pharmacy #6	335 Fourth Avenue, Huntington, WV, 25701	R	4,414,640	79,370,589	115,590,031
5	BT5541760	T and J Enterprises Inc DBA Medicine Shoppe	2402 Adams Avenue, Huntington, WV, 25704	R	3,945,310	56,985,703	80,381,260
11	BM9558733	McCloud Family Pharmacy	4541 5th Street Road, Huntington, WV, 25701	R	4,519,980	51,742,687	71,248,721
16	BD0427927	Drug Emporium	3 Mall Rd, Barboursville, WV, 25504	R	3,928,100	37,296,167	49,723,696
20	BR4365486	CVS/Pharmacy # 03391	2901 Fifth Ave, Huntington, WV, 25702	C	5,137,300	35,384,922	44,918,097
25	AF1585922	Fruth Pharmacy #5	#16 Perry Morris Square, Milton, WV, 25541	R	4,346,490	31,988,061	39,448,389
31	BS1588168	Fruth Pharmacy #12	1419-US Rt 60 East, Huntington, WV, 25705	R	4,997,620	31,030,947	36,542,089
36	BM9592381	Medical Park Pharmacy	5170 U.S. Route 60 East Suite 2800, Huntington, WV, 25705	R	2,684,760	23,901,727	31,782,773
41	BR4301545	CVS/Pharmacy # 04419	505 Twentieth Street, Huntington, WV, 25703	C	3,115,130	23,042,585	29,955,664
46	BR4321787	CVS/Pharmacy # 04425	447 W Washington Ave, Huntington, WV, 25701	C	3,582,100	23,124,310	28,564,116
51	AR6070178	Rite Aid #968	6401 US Route 60 East, Barboursville, WV, 25504	C	2,960,490	20,557,043	25,802,016
56	AS7523118	Fruth Pharmacy #2	125 Seventh Avenue, Huntington, WV, 25701	R	3,311,630	21,362,489	25,790,501
61	BM7641512	Medicap Pharmacy	4352 5th Street Road, Huntington, WV, 25701	R	1,955,540	18,004,432	23,821,498
66	AR6055025	CVS/Pharmacy # 03480	5179 US Route 60 East, Huntington, WV, 25705	C	2,370,100	16,689,210	21,320,213
71	BW5432947	Wal-Mart Pharmacy 10-2244	3333 US Route 60, Huntington, WV, 25705	C	3,290,080	16,914,298	19,276,396
76	FR0711552	Rite Aid #3423	527 31st Street, Huntington, WV, 25702	C	1,887,010	13,737,002	17,548,450
81	FA3535979	A+ Care Pharmacy	3 Chateau Lane, Barboursville, WV, 25504	R	583,000	11,724,025	17,365,587
84	FW1925568	Walgreens #11977	6414 US Rte 60 E, Barboursville, WV, 25504	C	1,297,510	12,352,862	16,600,765
88	BW8976322	Wal-Mart Pharmacy 10-5296	25 Nichols Drive, Barboursville, WV, 25504	C	2,456,980	13,488,906	15,747,212
93	BK5090941	Kroger Pharmacy #788	6360 U.S. Route 60, Barboursville, WV, 25504	C	2,087,670	12,323,270	14,578,377
98	BF1434555	Fruth Pharmacy #11	425 Camden Road, Huntington, WV, 25704	R	2,194,970	12,406,823	14,554,735
103	BR3421954	Rite Aid #3311	1010 South Main Street, Milton, WV, 25541	C	1,821,040	10,809,378	12,783,195
108	BK0386347	Kroger Pharmacy	#19 7th Ave. West, Huntington, WV, 25701	C	1,926,170	10,891,971	12,537,003
113	AC2986872	Rite Aid #950	1138 Hal Greer Boulevard, Huntington, WV, 25701	C	1,717,860	10,080,370	12,518,872
118	BK4885933	Kroger Pharmacy #792	2627 Fifth Avenue, Huntington, WV, 25702	C	1,868,660	10,645,245	12,401,601
123	FM1877402	Custom Script Pharmacy	3476 US Route 60 East, Barboursville, WV, 25504	R	441,100	7,989,295	11,769,634
127	BG6892625	G and R LLC DBA Budget Discount Pharmacy	361 Norway Avenue, Huntington, WV, 25705	R	1,134,270	8,361,161	10,702,572
131	FW1365748	Walgreens #11980	111 4th Ave., Huntington, WV, 25701	C	1,225,290	7,370,458	8,615,809
136	BM3744489	Medical Arts Supply DBA Medical Arts Phcy	949 Sixth Avenue, Huntington, WV, 25701	R	1,000,820	6,158,397	7,291,349
140	BS4645911	St Mary's Hospital Pharmacy (Outpatient)	2900 First Avenue, Huntington, WV, 25702	R	1,221,200	5,967,098	6,633,638
144	AK8905018	K Mart Pharmacy	5636 U.S. Route 60 E, Huntington, WV, 25705	C	1,068,560	5,606,270	6,389,295
149	BM6647739	Med Associates Pharmacy, Inc	#3 Chateau Lane, Barboursville, WV, 25504	R	558,590	3,936,580	4,928,723
153	FA3682348	Ross Drug	340 E Main St, Milton, WV, 25541	R	276,220	3,363,709	4,737,505
156	BT7982196	Target Store T-1478	2070 Thundering Herd Road, Barboursville, WV, 25504	C	641,070	3,752,977	4,455,720
160	BR3813664	Rite Aid Discnt Phcy #3423	418 Bridge Street, Huntington, WV, 25702	C	414,900	3,004,339	3,769,838

Moreover, there were significant warning signs that should have alerted Defendants things were going dangerously wrong with the opioids they were supplying.

For example, news reports detail how one pharmacy, SafeScript Pharmacy No. 6, formerly at 335 4th Ave., in Huntington, West Virginia, that Defendants fueled with over 100,000,000 MMEs of opioids in a 7 year window, was among the top five purchasers of Oxycodone in West Virginia and received the most oxycodone pills in Cabell County.[213] Between 2006 and 2013, this one pharmacy in Huntington, received over 4.4 million opioid pills.[214] As illustrated by Dr.

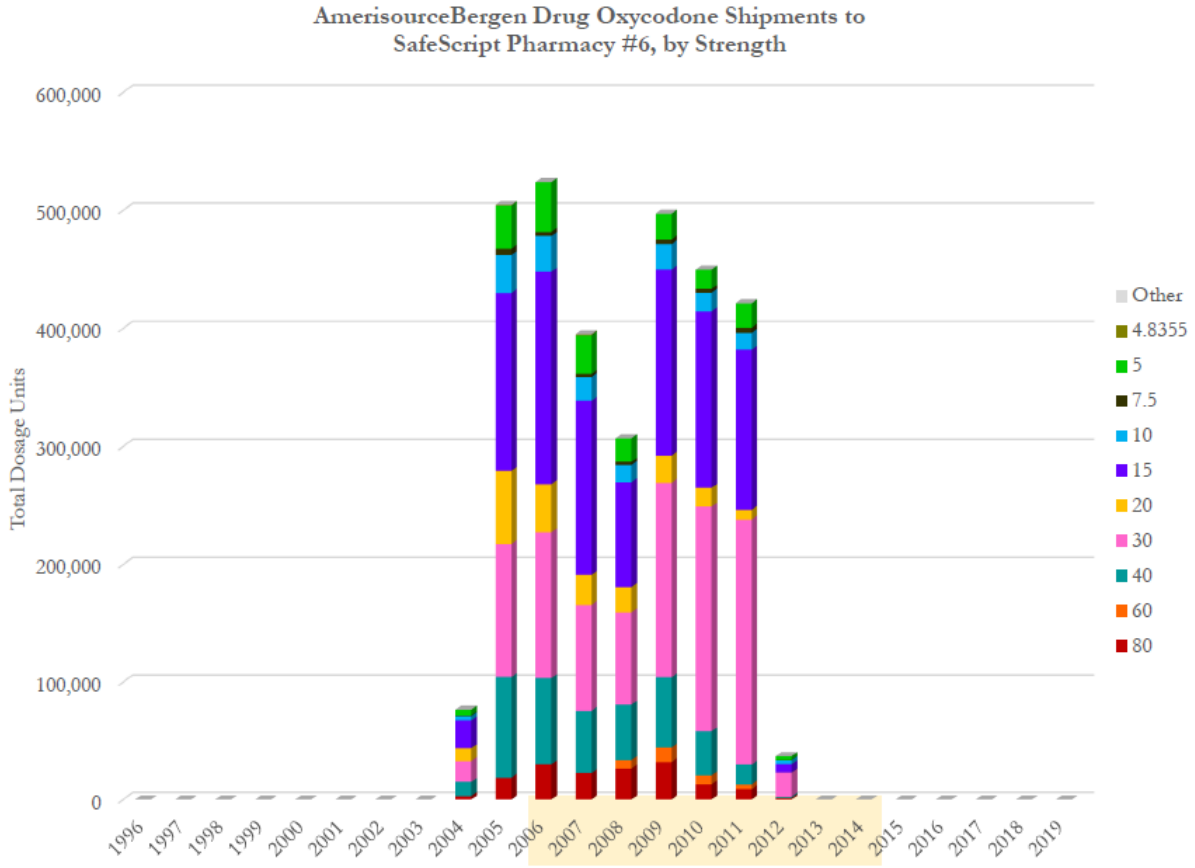
[212] Expert Report of Craig McCann, Appendix 9 at 544-545.

[213] https://www.herald-dispatch.com/_recent_news/more-than-65-million-opioids-flooded-cabell-county-over-7-years-data-shows/article_8f0d8676-a9a9-11e9-98ff-ebdd2586af3f.html.

[214] *Id.*; *see also* McCann Appendix 9 at 544.

McCann, a large portion of these pills were oxycodone 30mg pills, the most widely and notably abused forms of Oxycontin:[215]

SafeScript Pharmacy #6 (11/2004 to 2/2012)
DEA: BS8246349
335 Fourth Avenue
Huntington, WV 25701



Data source: ARCOS (2006-2014) and Defendant Transactional Data (ABDC 6/2002-12/2018)

Over time, the pharmacy's level of controlled substance purchasing rose to an alarming level of its total drug purchases, rising to 87% of its total purchasing from Amerisource Bergen, its primary distributor.[216] Its purchases landed SafeScript Pharmacy No. 6 on an internal AmerisourceBergen "top 100 purchase of OX products" list.[217] Internal correspondence at AmerisourceBergen shows that the company knew that customers on that list were servicing pain doctors without specializing in pain management and they "overwhelmingly" purchased oxycodone 30mg tablets.[218] Local news stories (found in AmerisourceBergen's files) describe

[215] Expert Report of Craig McCann, Appendix 9 at p. 781.

[216] ABDCMDL00170213.

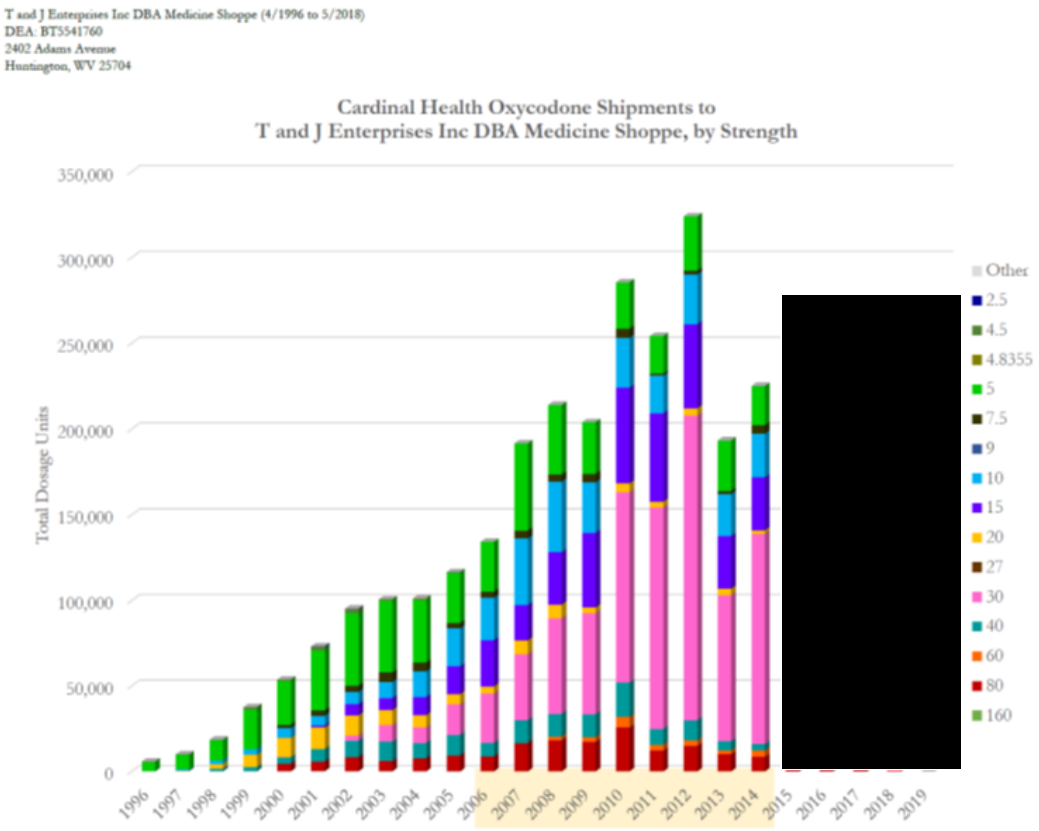
[217] ABDCMDL00280699.

[218] *Id.*

how it was not a "usual pharmacy" and that the pharmacy had "heavy security" and had installed bulletproof glass.[219] The media reports describe transactions being done through a turnstile where cash would go in and pills would come out.[220]

As detailed in the expert Report of James Rafalski, Amerisource Bergen continued to send opioids to SafeScript unchecked until 2013, even despite triggering numerous internal tripwires and exceeding controlled substance thresholds.[221] The only thing that stopped Amerisource Bergen was when SafeScript Pharmacy No. 6 owner was charged with felony drug possession and trafficking thousands of hydrocodone tablets to street dealers.[222]

Other distributors were also selling large numbers of the most easily abused, high dose opioids into Cabell County, including oxycodone 30mg:[223]



[219] ABDCMDL04476169.

[220] *Id.*

[221] *See generally* Expert Report of James Rafalski at 111-114.

[222] *Id.*

[223] McCann Report at Appendix 9, at 818.

There were numerous other warning signs.[224] Indeed, a simple review of commercially available data regarding community prescribers would have alerted Defendants that something was going very wrong with the opioids they were supplying into the Cabell-Huntington Community.[225] IQVIA data showed the total volume of opioid prescriptions in the community dramatically increasing, as well as the number of pills and MMEs per prescription.[226]

Table 1 Annual Opioid Prescriptions
(IQVIA Xponent®: Cabell County, 1997-2017)
This table is sorted chronologically. Percent increases are calculated to the base year of the data (1997).

Year	Opioid Prescriptions	Cumulative Prescriptions	% Increase In Prescriptions	Opioid Dosage Units	Cumulative Dosage Units	% Increase In Dosage Units	Opioid MMEs	Cumulative MMEs	% Increase In MMEs
1997	80,922	80,922	0.0	3,834,550	3,834,550	0.0	30,634,978	30,634,978	0.0
1998	90,560	171,482	11.9	4,519,034	8,353,584	17.9	39,499,506	70,134,484	28.9
1999	103,065	274,547	27.4	5,319,945	13,673,529	38.7	51,979,153	122,113,637	69.7
2000	115,150	389,697	42.3	6,073,883	19,747,412	58.4	71,206,610	193,320,247	132.4
2001	123,461	513,159	52.6	6,981,659	26,729,071	82.1	89,575,799	282,896,046	192.4
2002	137,445	650,603	69.8	8,226,235	34,955,307	114.5	112,509,249	395,405,294	267.3
2003	154,105	804,708	90.4	9,742,686	44,697,992	154.1	139,034,472	534,439,767	353.8
2004	162,029	966,737	100.2	10,409,058	55,107,050	171.4	142,217,424	676,657,190	364.2
2005	179,750	1,146,487	122.1	11,609,337	66,716,387	202.8	160,076,543	836,733,733	422.5
2006	202,358	1,348,845	150.1	13,500,799	80,217,185	252.1	181,925,922	1,018,659,654	493.9
2007	219,660	1,568,505	171.4	14,807,674	95,024,860	286.2	203,088,509	1,221,748,163	562.9
2008	217,264	1,785,768	168.5	14,752,415	109,777,274	284.7	212,599,803	1,434,347,966	594.0
2009	215,237	2,001,005	166.0	15,164,944	124,942,218	295.5	237,450,981	1,671,798,947	675.1
2010	209,121	2,210,127	158.4	14,897,686	139,839,905	288.5	253,398,773	1,925,197,720	727.2
2011	203,904	2,414,031	152.0	14,117,053	153,956,958	268.1	227,969,326	2,153,167,046	644.1
2012	180,904	2,594,935	123.5	12,087,838	166,044,796	215.2	181,296,487	2,334,463,533	491.8
2013	166,846	2,761,780	106.2	11,287,907	177,332,703	194.4	169,322,642	2,503,786,176	452.7
2014	165,163	2,926,944	104.1	11,422,743	188,755,446	197.9	179,710,770	2,683,496,945	486.6
2015	142,237	3,069,181	75.8	10,241,332	198,996,778	167.1	162,048,969	2,845,545,914	429.0
2016	123,845	3,193,026	53.0	8,949,442	207,946,220	133.4	142,983,573	2,988,529,488	366.7
2017	102,374	3,295,400	26.5	7,096,503	215,042,723	85.1	87,995,608	3,076,525,096	187.2

[224] *See generally* Expert Report of James Rafalski, Expert Report of Craig McCann.

[225] *See* Expert Report of Lacy Keller analyzing IQVIA data, the data "gold standard in terms of understanding prescription trends." IQVIA is proprietary and available for purchase by pharmaceutical companies, including the Defendants had they chose to purchase it.

[226] Keller Report at ¶22 and Table 1.

The data showed that a small number of pain doctors were writing a large amount of prescriptions:[227]

Table 2 Opioid-Prescribing Specialties with Per Physician and Prescription Averages (IQVIA Xponent®: Cabell County, 1997-2017)
This table is sorted by descending average dosage units per prescriber.

Prescriber Specialty	Opioid Prescribers	Average Prescriptions Per Prescriber	Average Dosage Units Per Prescriber	Average Dosage Units Per Prescription	Average MMEs Per Prescriber	Avg MMEs Per Prescription
PAIN MEDICINE	6	2,478	210,529	85	6,189,932	2,498
PHYSICAL/OCCUPATIONAL REHABILITATION	5	1,311	114,645	87	2,695,439	2,056
RHEUMATOLOGY	3	1,055	107,566	102	1,084,962	1,028
ANESTHESIOLOGY	23	423	29,016	69	550,925	1,302
ADDICTION	1	331	22,624	68	681,629	2,057
NEUROLOGY	21	359	21,375	60	169,219	472
ONCOLOGY	18	205	19,974	97	309,309	1,507
ORTHOPEDICS	6	292	12,845	44	96,735	331
FAMILY/GENERAL	441	143	10,721	75	127,764	892
HEMATOLOGY/PHLEBOTOMY	4	109	9,903	91	194,088	1,776
UROLOGY	14	231	7,498	33	56,079	243
SURGERY	108	156	7,027	45	37,456	241
GERIATRICS	2	81	5,708	70	90,325	1,110
NEPHROLOGY	6	67	4,781	72	41,124	618
EMERGENCY/CRITICAL	39	174	4,530	26	32,380	186
CARDIOLOGY	33	47	3,461	74	30,688	652
OTHER SPECIALTY	24	74	2,725	37	19,179	258
ENDOCRINOLOGY	15	29	2,260	78	20,604	711
OBSTETRICS/GYNECOLOGY	70	83	2,118	26	14,187	172
PSYCHIATRY	52	33	2,096	64	34,641	1,056
PATHOLOGY/EPIDEMIOLOGY	14	32	1,805	56	22,686	705
PULMONOLOGY	7	25	1,590	64	16,221	658
DENTISTRY	69	70	1,329	19	7,839	113
ADMINISTRATIVE/MANAGEMENT	7	30	1,188	40	11,157	372
GASTROENTEROLOGY	10	15	1,183	80	13,579	916
PEDIATRICS	46	20	637	33	3,565	182
ALLERGY/IMMUNOLOGY	1	9	548	63	3,067	355
DERMATOLOGY	6	17	432	25	3,514	204
AEROSPACE/HYPERBARIC/NUCLEAR	1	7	315	48	963	147
PHARMACOLOGY	1	7	314	45	2,020	287
OPHTHALMOLOGY	15	13	304	24	2,043	160
OTHER/UNSPECIFIED SPECIALTY	17	7	252	34	1,847	252
RADIOLOGY	21	4	94	22	598	140
VETERINARY	19	1	39	40	383	392

And when the data is examined some egregious examples over overprescribing evidencing criminal activity and diversion were apparent. Indeed, one of these high prescribing pain doctors, Dr. Deleno Webb. had been barred by the West Virginia Workers' Compensation Commission in 2005 from receiving payment for treating injured workers based on claims that he was prescribing Oxycontin without conducting physical examinations. .[228, 229] Between 1998 and 2016, however, he rose to becoming one of the top five prescribers in Cabell County,. in

[227] *Id.* at Table7.

[228] Keller Report at 20; *citing* https://www.claimsjournal.com/news/southeast/2005/07/05/56882.htm;

[229] *Id. citing* PPLPC031000256122.

seven of those years, prescribing more opioid dosage units and MMEs than any other physician in Cabell County.[230] In fact, in 2002 and 2003, Webb was the leading prescriber of opioid dosage units and MMEs in West Virginia.[231] Webb prescribed more than 10 million dosage units of oxycodone alone, ranking first in the state for overall for prescriptions, dosage units, and MMEs.[232]

By 2011, Dr. Webb was prescribing over 1.1 million dosage units – the equivalent of more than 130 pills every hour of every day.[233] Over 30% of the dosage units Webb wrote were for oxycodone 30mg, known to be a highly abused opioid.[234] Webb continued prescribing opioids for more than a decade, until voluntarily surrendering his medical license in 2017. An investigation had found that he "commonly treated the patients with excessive dosages of opiates and benzodiazepines," among other claims.[235]

Additionally, data shows that pills were flooding the community through Anita Dawson, a Doctor of Osteopathic Medicine. Anita Dawson ranked third in Cabell County for overall dosage units prescribed during the IQVIA period.[236] From 2006 through 2009, Dawson was writing prescriptions for over one million dosage units per year – more than 100,000 dosage units more per month than the average general practitioner in the state and nation. The average strength and dosage units per prescription increased almost every year she practiced until she was arrested, peaking at an average of 130 dosage units and 2,227 per prescription in 2010. The year before, she prescribed over 1.4 million dosage units – or 3,800 pills per day, including weekends and holidays.

In April, 2010, Dr. Dawson's license was suspended[237] and in July 2012, Dawson pled guilty to aiding and abetting the illegal acquisition of prescription drugs and was sentenced in January 2013 to two years in federal prison.[238] Nine patients' deaths were attributed to Dr. Dawson's

230 *Id.*

231 *Id.* at 21.

232 *Id.*

233 *Id.*

234 *Id.*

235 *Id. citing* https://wvbom.wv.gov/public/search/index.asp

236 *Id.*

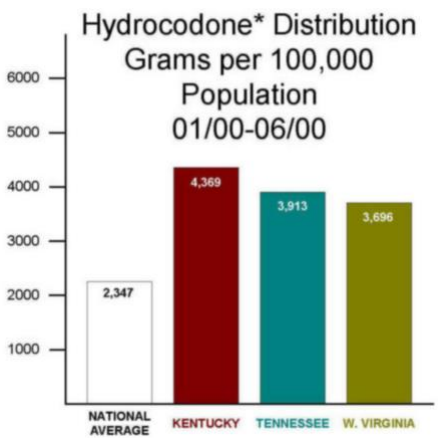
237 Complaint. West Virginia Board of Osteopathy v. Anita Dawson, Complaint No. 10-05, *available at*, https://www.justice.gov/archive/usao/wvs/press_releases/June2012/attachments/DawsonChargesSuspension.pdf.

238 "Cabell County Doctor Sentenced to Two Years in Prison for Federal Drug Crime." *FBI, Pittsburgh Division.* 7 January 2013. https://archives.fbi.gov/archives/pittsburgh/press-releases/2013/cabell-county-doctor-sentenced-to-two-years-in-prison-for-federal-drug-crime.

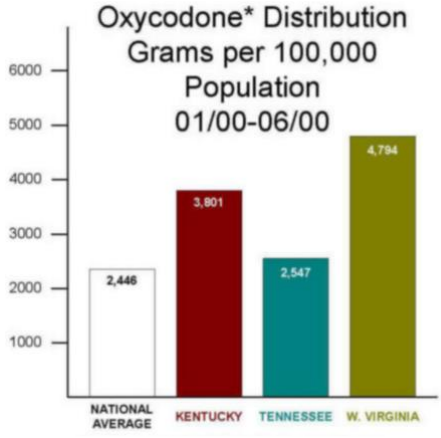
prescribing patterns, including one patient who caused a fatal car crash while under the influence of opioids prescribed by Dawson.[239]

These stunning examples were but symptoms of a larger picture that Defendants recklessly ignored. Indeed, Defendants were flooding West Virginia and the Cabell Community with high dosage opioids and failing to investigate warning signs for diversion.[240] Defendants' systems to evaluate and prevent diversion were demonstrably inadequate. It is clear that the Defendants failed in their obligation as DEA registrants.

Diversion was rampant in West Virginia by the early 2000s and has continued to be a catastrophic problem to the present day.[241] In 2000, a report by the Appalachia High Intensity Drug Trafficking Area program (AHIDTA) showed an increase in the resale and abuse of prescription drugs within a three-state region, including West Virginia.[242] The report noted that agencies from the states were targeting physicians who prescribed medication to "doctor shoppers" and overcharged Medicaid/Medicare making enormous profits.[243]



[244]



[245]

[239] *Id.*

[240] McCann Appendix 9; *see also* Keller Report at 24 and Table 14.

[241]. Congressional Report at 25; *citing* Hall, A., et al. (2008). *Patterns of Abuse Among Unintentional Pharmaceutical Overdose Fatalities JAMA*, 300(22), 2613, 2619; U.S. Department of Justice National Drug Intelligence Center Report, *Drug Market Analysis 2008: Appalachia High Intensity Drug Trafficking Area* (2008).

[242] Vic Brown [AHIDTA] Deposition (July 8, 2020) at 66:20-73:6; Brown Deposition Ex. 2, AHIDTA_0404-425(2000 AHIDTA Annual Report).

[243] *Id.*

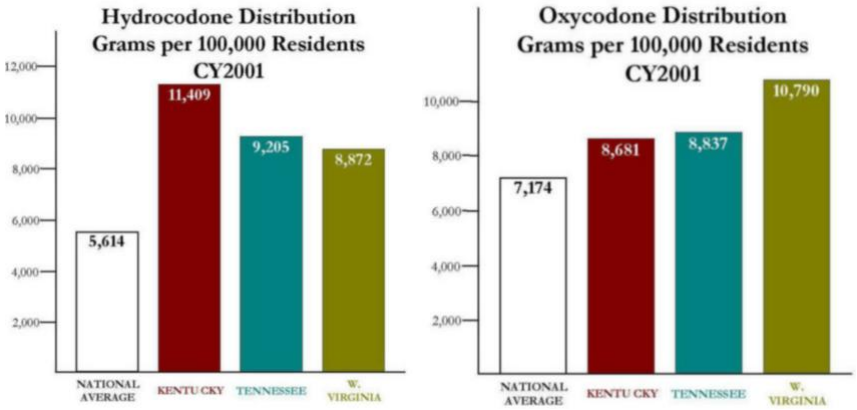
[244] Vic Brown Deposition at 103:6-108:17; Brown Deposition Ex. 8, AHIDTA_0972-1014 (2002 AHIDTA Threat Assessment).

[245] *Id.*

By 2001, prescription drug seizures accounted for 23% of the "other" drugs seized by AHIDTA officers. AHIIDTA noted:

> However, this relatively low seizure rate does not indicate the seriousness of the impact of the illicit use and trafficking of prescription drugs in the area. The trafficking and illicit usage of prescription drug use in the area may well be the most significant drug problem aside from marijuana.[246]

The report indicated a massive supply of both oxycodone and hydrocodone into the region.[247]



The report continued:[248]

> OxyContin addiction is the root cause of a range of criminal activity in the Appalachia HIDTA, such as robbery, theft, assault, and various types of prescription fraud. In CY2000, Kentucky and West Virginia have seen an alarming increase in pharmacy robberies and thefts. In many cases the perpetrators ignored the cash, interest only in obtaining OxyContin tablets.

Indeed, by 2001 the United States Department of Justice issued a warning about widespread diversion of Oxycontin[249] and in 2003 the United States GAO issued a report discussing issues

[246] Vic Brown Deposition at 71:15-73:6; Brown Deposition Ex. 5, AHIDTA_0905-947 (2001 AHIDTA Threat Assessment).

[247] Vic Brown Deposition at 73:10-74:10; Brown Deposition Ex. 17, AHIDTA_1168-1215 (2005 AHIDTA Threat Assessment).

[248] *Id.*

[249] U.S. Department of Justice, *Information Bulletin: Oxycontin Diversion and Abuse*, Product No. 2001-L0424-001 (January 2001); U.S. Department of Justice, U.S. Drug Enforcement Administration, *Alert: Working to Prevent the Diversion and Abuse of OxyContin*, July 2001.

with diversion.[250] In 2005, the DEA launched the Distributor Initiative aimed at addressing the problem of rampant diversion.[251] Years of citations and penalties followed where company after company, including Defendants were cited for failing to comply with their obligations to detect and prevent obvious diversion.[252] Problems with diversion that persist with such a massive supply of opioids has been a devastating problem ever since.[253]

Local witnesses from the Cabell- Huntington Community describe how diversion was rampant and how the wave of diversion Defendants failed to prevent has overwhelmed public health and safety departments and has produced lasting and devastating effects on the community (see also, p. 23, above and depositions listed in Schedule 3):

- Hank Dial, City Manager for the City of Huntington and former Police Chief for the City of Huntington, testified that the drug problem in Huntington is so pervasive that every aspect of the police department had to deal with it: "[i]t was so encompassing, it affected every bureau."[254]

- Rocky Johnson, former member of the Huntington Police Department Special Investigations Bureau, testified about doing everything within its ability to address the opioid crisis, at their own peril, stating "police officers with our mental health, you know, and the fatigue, the compassion fatigue of seeing all this death and destruction and all of this."[255]

- According to Gordon Merry, Director of Cabell County EMS, "Basically the challenges we've had with it with the overdoses. It has definitely taxed our system. It's been --It's just caused a lot of problems with personnel. Unfortunately, I just can't say anything good dealing with it. It's been horrible."[256]

- Mr. Merry went on to describe, "It's been a very, very horrible experience. I wouldn't wish this on anybody. Medics have left. Going into houses where the mothers have overdosed and the kids are sitting there crying, wanting to know what's wrong with their

[250] U.S. Government Accountability Office (GAO), *Prescription Drugs: Oxycontin Abuse and Diversion and Efforts to Address the Problem*. Washington, DC: GAO, *available at,* https://www.gao.gov/assets/250/240884.pdf.

[251] Congressional Report at 31-35; *see* Section VI(4)(e). below.

[252] *See* Section VI(4)(e).

[253] Mars, S. et al. (2014). "Every 'Never' I Ever Said Came True": Transitions from opioid pills to heroin injecting. Int J Drug Policy, 25(2), 257–266. doi: 10.1016/j.drugpo.2013.10.004.

[254] Hank Dial [Cabell] Deposition (June 25, 2020) at 78:21-22.

[255] Rocky Johnson [Cabell] Deposition (June 26, 2020) at 131:22-24.

[256] Gordon Merry [Huntington] Deposition (July 29, 2020) at 35:21-36:1.

> mother. It's mentally -- and it's definitely taken its toll on the staff, turnovers, horrible. And it's not just EMS. It's police, fire, EMS and hospitals. It's answering the same call or answering the call for the same person two to three times a day. It was a revolving door, on top of their normal calls they had to answer. And the stress level was very high."[257]

Defendants were repeatedly cited for failing to meet their obligations to prevent diversion and protect the public health (see Section VI(4)(e)below). Additionally, I have reviewed the Expert Report of James Rafalski, who opines about the nonexistent or woefully inadequate systems Defendants had to prevent diversion.

Over and over, Defendants internally acknowledged the inadequacy of their own systems to prevent diversion.[258] For example, in 2007, a Cardinal Health employee raised the issue of Cardinal's deficient systems, telling the Cardinal compliance department that:[259]

> The manual process we perform now with the discovery of suspected excessive purchases being left up to the keyer notifying myself, or a picker/double checker/QCer questioning an amount being processed seems to leave ample opportunity for failure. A system generated "flag" would be a more complete or thorough method of determining spikes or excessive quantities than what we are currently performing.
>
> As you know, I've investigated many accounts, tracked their ordering history, and reached out for guidance and directions. But without "someone" bringing a suspected "excessive quantity" order to our attention, many, many more could be going out the door under our noses. I wonder could a similar situation happen in Lakeland and management be questioned "why wasn't this discovered?

McKesson made clear, however, it was more interested in profits than in having meaningful systems in place to prevent diversion, stating that "**[w]e are in the business to sell product.** If we could produce a report … that warned as customers approach to the threshold, say at 85% of their 10,000 dosages, work could begin on justifying an increase in threshold prior to any lost sales."[260]

[257] Gordon Merry [Huntington] Deposition (July 29, 2020) at 36:9-20.

[258] *See e.g.* CAH_MDL2804_03309960; CAH_MDL_PRIORPROD_DEA07_00135433; Sharon Hartman [AmerisourceBergen] Deposition at 17:11-16, 236:5-13 and Hartman Deposition Ex. 13; CAH_MDL_PRIORPROD_DEA07_00968964; MCKMDL00634329 at 00634331; MCKMDL00634329 at330-331; MCKMDL00516748-754; MCKMDL00409224-235; MCKMDL00721376-379; MCKMDL00721376 at 00721383; MCKMDL00721376 at 00721384-85; MCKMDL00498057 at 069-70; MCKMDL00721366 at 00721372; MCKMDL00827928; MCKMDL01940693; MCKMDL00721366-373; MCKMDL00721366-375; MCKMDL0045097-977. MCKMDL00450972-976; MCKMDL0045097-976; MCKMDL00450972 at 00451005-06; ABDCMDL00274105-118; ABDCMDL00250024-063.

[259] CAH_MDL_PRIORPROD_DEA07_00135433.

[260] MCKMDL00543971 at 972

Given Defendants clear duties to design adequate systems to prevent diversion, and their clear failure to do so, it was reckless and unreasonable for Defendants to continue doing "business as usual."

The flood of pills into West Virginia was staggering, especially in light of the developing Opioid Epidemic in West Virginia and the United States. Sending a flood of pills into a community with no meaningful way to control improper supply and diversion, was reckless and dangerous. The sheer volume of pills Defendants sold into West Virginia and the Cabell-Huntington Community, coupled with the lack effective mechanisms to control that supply, made it foreseeable and inevitable that diversion, abuse, addiction, misuse, overdose and death would occur. *See* Testimony of Community witnesses, herein and as listed in the Schedule. Indeed, with increased exposure to prescription opioids, significant risks to public health will occur. Increasing a population's exposure to a highly addictive drug will cause an increase in addiction and an array of health and social problems.

Defendants' actions in irresponsibly overexposing the population to such a massive volume of highly addictive drugs, without mechanisms to protect that population, was a substantial factor in creating the Opioid Epidemic in the Cabell Huntington Community.

Over time, Defendants have lodged a variety of excuses for not meeting their obligations under federal law and any reasonable standard for those distributing a dangerous narcotic in a closed system. The Defendants appear to have first claimed they didn't know what was expected of them under the CSA:

- "At different points in time, the expectations of the DEA were different."[261]

- "To the best of my knowledge, until 2005, regulators did not articulate an expectation that distributors actively conduct due diligence regarding their downstream customers beyond the reporting of suspicious orders pursuant to 21 C.F.R. § 1301.74(d)."[262]

- "I believe that our organization [Cardinal] understood the responsibilities and conducted them as best they could with the understanding at that time."[263]

- "In the past we've [McKesson] had challenges understanding the expectations that our regulator would like us to follow."[264]

[261] *See* Transcript of 5/8/2018 Hearing of U.S. House Committee on Energy and Commerce (testimony of Christopher Smith, H.D. Smith former President & CEO) at p. 75.

[262] *See* CAH_MDL2804_01454458 (Supplemental Declaration of Michael Mone, *In the Matter of Cardinal Health*, at p. 4, ¶ 9 (4/13/2012)).

[263] *See* Transcript of 5/8/2018 Hearing of U.S. House Committee on Energy and Commerce (testimony of George Barrett, Cardinal Executive Chairman of Board) at p. 45.

[264] *See* Transcript of 5/8/2018 Hearing of U.S. House Committee on Energy and Commerce (testimony of John Hammergren, McKesson President & CEO) at p. 46.

- "DEA's shift in expectations for suspicious order monitoring caused 'confusion in the industry.'"[265]

These excuses fall flat as their requirements remained nearly unchanged since 1970[266] and in light of the fact that the DEA, between 2005 and 2007, conducted multiple meetings with each Defendant, explaining the rules, their requirements and what they must do to comply in one-on-one meetings.[267]

Defendants also have claimed they did "the best they could" with their technology and information at the time:

- "Our [McKesson's] systems at the time were not automated enough, certainly, and we didn't flag it fast enough and get it fast enough."[268]

- "We [McKesson] certainly learned, Mr. Chairman, from that experience at Sav-Rite, and we realized that we needed automated systems that don't allow any order to ship out of our facilities that are past those thresholds."[269]

- "Certainly, we've [McKesson] learned from our experience during the 2006, 2007, over a decade ago, and today's systems are much more robust than they were then. Our orders actually aren't even processed today if they're above thresholds. In those early phases of 12 years ago, our systems weren't as automated as they are today."[270]

- "I'm not sure, Congresswoman, that I [Cardinal] could say that we were failing to reflect that. I think we were using the tools of the moment. And it was probably much more subjective judgment than what would happen today. Today it is a much more rigorous, evidence-based, data-based decision, and it doesn't have the same kind of subjectively I think that was present at that moment."[271]

[265] *See* 7/31/2019 Defendants' Response to Plaintiffs' Motion for Partial Summary Adjudication on Defendants' Compliance With the Controlled Substances Act [CSA Compliance Brief] at p. 9.

[266] Congressional Report at 28.

[267] *See* Section below and documents cited therein.

[268] *See* Transcript of 5/8/2018 Hearing of U.S. House Committee on Energy and Commerce (testimony of John Hammergren, McKesson President & CEO) at p. 55.

[269] *Id.* at p. 56.

[270] *Id.* at p. 74.

[271] *See* Transcript of 5/8/2018 Hearing of U.S. House Committee on Energy and Commerce (testimony of George Barrett, Cardinal Executive Chairman of Board) at p. 98.

This argument also does not pass muster. Indeed, these are some of the largest and most sophisticated companies in the world who had at their disposal sophisticated systems to track each pill through the system, the ability to see hot spots for distribution at the click of a button and to analyze distribution and sales on a geographic basis. They had numerous data sources that they could have consulted in order to get a more accurate picture of compliance.[272] Indeed, from these data sources we see red flags that should have caused Defendants to look more closely at what was happening in the Cabell-Huntington Community. If they did not see the whole picture, they chose not to.

Nevertheless, if Defendants found it impossible to design an adequate system to prevent opioids diversion because of the obstacles they identify, then it was utterly reckless and unreasonable for Defendants to continue supplying opioid products and supplying them in the amounts they did.

c. The Defendants continued to dramatically increase the supply of prescription opioids despite mounting evidence of that opioid manufacturers were illegally promoting their products, that there was massive diversion of opioids and that a public health epidemic was resulting.

By the early 2000s, there were signs of a burgeoning epidemic of opioid addiction, overdose, diversion and death, especially in West Virginia. Indeed, reports of addiction, overdose, diversion and death in in certain hot spots around the country, including in West Virginia, started appearing in the headlines of the news nationally and in the local papers where each of the Defendants were located.[273]

[272] *See generally* Keller Report.

[273] *See e.g. The Alchemy of Oxycontin*, July 29, 2001. N.Y. Times, available at https://www.nytimes.com/2001/07/29/magazine/the-alchemy-of-oxycontin.html; "'Hillbilly Heroin' Holds Appalachia in Its Grip of Death and Addiction," June 17, 2001, LA Times, available at https://www.latimes.com/archives/la-xpm-2001-jun-17-mn-11349-story.html; *28 Deaths Linked to Drug: Oxycontin Plagues Southwest Virginia*, February 9, 2001, Richmond Times Dispatch (Virginia); *Painkiller Stirs Concern, Debate: Meeting on Key Brand is* Today, March 1, 2001, Richmond Times Dispatch (Virginia); *No Matter What you Call It, It's Still Just Plain Ol' Dope*, March 18, 2001, Richmond Times Dispatch (Virginia)*Drug's Abuse Concerns FDA*, March 23, 2001, Richmond Times Dispatch (Virginia); *Abuse of Drug 'Getting Worse*,' May 18, 2001, Richmond Times Dispatch (Virginia); *A drug challenge*, Intelligencer Journal (Lancaster, PA.); Scott Finn and Tara Tuckwiller, *The Killer Cure: Deaths tied to methadone escalate across state, nation*, June 4, 2006, Charleston Gazette-Mail, available at https://www.wvgazettemail.com/news/special_reports/deaths-tied-tomethadone-escalate-across-state-nation/article_9a021a7d-b1f8-5f50-9711-17a5c9b182f7.html;Tom Breen, *Hydrocodone Abuse on the Rise in Appalachia*, Aug. 21, 2001, Associated Press reprinted in Washington Post, available at http://www.washingtonpost.com/wp-dyn/content/article/2007/08/21/AR2007082100146.html ; *A Painful Abuse; Addicts' use hurts legitimate patients, too*, Oct. 2, 2001, Columbus Dispatch (Ohio); *Pilfering Pills* Jul. 18, 2001, Columbus Dispatch (Ohio); *More Overdose Deaths Blamed on Painkiller*, Jan. 6, 2002, Columbus Dispatch (Ohio); *Heroin substitute grows in popularity; Drug is in county, but not yet widely used*, Jan. 4, 2001,Intelligencer Journal (Lancaster, PA); *Sen. Warner Calls for Drug Hearing*, Aug. 1, 2001, Richmond Times Dispatch (Virginia); Tom Breen, *Hydrocodone Abuse on the Rise in Appalachia*, Associated Press reprinted in WASH. POST, Aug. 21, 2007, available at

In 2001, the United States House of Representatives Energy and Commerce Committee began an investigation into Oxycontin's use and abuse and held public hearings where Defendants' business partner Purdue was called to answer questions about the emerging devastation that was resulting regarding the pills Defendants were supplying.[274] The committee heard public testimony about the severity of Oxycontin abuse including that it was "quickly becoming the abuser's drug of choice, surpassing heroin and cocaine in some jurisdictions"[275] and that law enforcement officials believed that the Defendants' business partner, Purdue Pharma, had engaged in "overly aggressive marketing practices and a failure to swiftly respond once the abuse of OxyContin was first reported" and detailed the false marketing campaign to persuade doctors that opioids could be prescribed for routine pain conditions over long periods of time.[276] The Committee heard that diversion and abuse of this prescription opioid was rampant and acutely so in West Virginia.[277] The committee publicly raised the severe and burgeoning health epidemic that was just beginning, pointing to the direct correlation between that epidemic and prescription opioids stating that "[a]ccording to DEA, the number of Oxycodone-related deaths has increased 400 percent since 1996, the same time period in which the annual number of prescriptions for OxyContin has risen from approximately 300,000 to almost 6 million."[278]

Between 2001 and 2007, the United States government issued numerous public warnings about the growing crisis of prescription opioid addiction, abuse, diversion, overdose and death including:

- In January 2001, the United States Department of Department of Justice, DEA Intelligence Bulletin issued a bulletin to industry specifically detailing the public health and safety consequences that were occurring because of increased supply of prescription opioids, specifically detailing those effects in West Virginia.[279]

http://www.washingtonpost.com/wp-dyn/content/article/2007/08/21/AR2007082100146.html; *see* **Schedule 3**.

[274] Congressional Hearing. *Oxycontin: It's Use and Abuse*, Transcript of the Hearing Before the Subcommittee on Energy and Commerce, House of Representatives, One Hundred and Seventh Congress, First Session, August 28, 2001.

[275] *Id.*

[276] *Id.*

[277] *Id.*

[278] *Id.*

[279] U.S. Department of Justice, *Information Bulletin: Oxycontin Diversion and Abuse*, Product No. 2001-L0424-001 (January 2001), available at https://www.justice.gov/archive/ndic/pubs10/10550/index.htm.

- In July 2001, the United States DEA issued an alert to industry about the rampant abuse and diversion that had arisen regarding Oxycontin.[280]

- In 2002, the United States Department of Justice, OIG issued a report noting rampant Oxycontin abuse in West Virginia and making clear to all involved the DEA did not have sufficient resources to address the significant problems with prescription opioid diversion in the United States.[281]

- In 2003, the United States Governmental Accountability Office issued a report detailing improper marketing by Defendants' business partner Purdue and outlining the burgeoning health and safety crisis in the United States, and acutely in West Virginia, making clear the opioid drugs Defendants were supplying were no different than heroin.[282]

- August 2004, the United States Department of Justice, DEA Intelligence Bulletin issued a bulletin to industry about rampant abuse and diversion of Oxycontin citing National Drug Threat Survey 2003 (NDTS) data collected by the National Drug Intelligence Center (NDIC) reporting that "67.0 percent of state and local law enforcement agencies report that OxyContin is commonly diverted and abused in their areas—a higher percentage than any other pharmaceutical drug" and highlighting issues of increasing dosage, tolerance, abuse and addiction, respiratory depression and death.[283]

- In 2005, the United States Department of Justice, DEA embarks on a campaign directed at industry, including the Defendants called the "Distributor Initiative" directed at addressing the serious problems with prescription opioid diversion, addiction, abuse, overdose and death in the United States.[284]

- In 2006, the United States Centers for Disease Control published a paper showing that opioid overdose deaths had increased in parallel with an increase in sales of opioids.[285]

[280] U.S. Department of Justice, Drug Enforcement Administration, *Alert: Working to Prevent the Diversion and Abuse of OxyContin*, July 2001.

[281] 2018 Congressional Report at 47-48; *citing* U.S. Office of the Inspector General, Review of the Drug Enforcement Administration's Investigations of the Diversion of Controlled Pharmaceuticals. (Sept. 2002) (attached as Ex. 518 to McKesson witness, Michael Oriente July 19, 2018 deposition).

[282] U.S. Governmental Accountability Office, Report to Congressional Requesters, "Prescription Drugs: Oxycontin Abuse and Diversion and Efforts to Address the Problem," GAO-04-110 (December 2003).

[283] U.S. Department of Justice, "Information Bulletin: Oxycontin Diversion and Abuse," Product No. Product No. 2004-L0424-017 (August 2004)

[284] *See* Section 5(e), below.

[285] Paulozzi LJ, et al. (2006). Increasing deaths from opioid analgesics in the United States. *Pharmacoepidemiol Drug Saf.*, 15(9), 618-627. doi: 10.1002/pds.1276

- In 2007, Defendants' business partner Purdue Pharma publicly plead guilty to criminal misconduct amid a public health epidemic.[286]

- In 2008, Cephalon Inc. entered a criminal plea and paid $425 million in criminal and civil penalties to resolve claims that it marketed opioid drugs for uses not approved by the Food and Drug Administration (FDA).[287]

Since 2008, the public health crisis precipitated by prescription opioids was summarized in numerous news articles, books and media stories,[288] and governmental bodies and task force groups have reported on the public health and safety disaster created by the massive supply of prescription opioids including:[289]

- The CDC reported in a data briefing that between 1999 and 2016, 351,000 lives had been lost to opioid overdoses in the United States.[290]

- In 2007 the DEA issued a fact sheet summarizing massive diversion in West Virginia.[291]

- In 2011, the CDC issued a report entitled *Vital Signs: Overdoses of Prescription Opioid Pain Relievers --- United States, 1999—2008,* concluding that "The epidemic of

[286] B. Meier, *In Guilty Plea, OxyContin Maker to Pay $600 Million,* NY Times, May 10, 2007 at https://www.nytimes.com/2007/05/10/business/11drug-web.html; *Purdue Fredrick Pleads Guilty in Oxycontin Case*, Reuters, May 10, 2007 at https://www.reuters.com/article/us-oxycontin-misbranding/purdue-frederick-pleads-guilty-in-oxycontin-case-idUSWBT00695020070510.

[287] https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html

[288] *See How Obama Plans To Combat Prescription Opioid And Heroin Abuse In 2016*. Forbes, Feb 6, 2015.; *How Should the U.S. Regulate Powerful Painkillers?* PBS NewsHour, Jan 6, 2015.;"*Groups unite against curbing painkillers*. Boston Globe. Dec 29, 2014.; *Opioids prescribed by doctors led to 92,000 overdoses in ERs in one year*. LA Times, Oct 27, 2014.; *Overdose deaths spur families to march on Mall over Opioid Epidemic*. Washington Post, Sep 28, 2014.; *Heroin's Death Toll Rising in New York, Amid a Shift in Who Uses It*. New York Times, Aug, 28, 2014.; "*Painkiller Paradox: Feds Struggle To Control Drugs That Help And Harm*. NPR, Jan 23, 2012.; *Rising Painkiller Addiction Shows Damage From Drugmakers' Role in Shaping Medical Opinion.* Washington Post, Dec 30, 2012.; *Prescription for Addiction*. Wall Street Journal, Oct 5, 2012.; *Lobbying Effort Said to sink New Controls on Painkillers*. New York Times, Jun 19, 2012, Page A14.; *Senate Inquiry Into Painkiller Makers' Ties*. New York Times, May 9, 2012, Page B7.; *U.S. Consumes 80% of World's Oxycodone*. Newsday, Jan 21, 2012.; *OxyContin: Purdue Pharma's Painful Medicine*. Fortune Magazine, Nov 9, 2011.; *Champion of Painkillers*." Washington Post, Dec 23, 2011.; *White House Plan to Target Painkiller Abuse*. ABC News, Apr 25, 2011.

[289] *See* **Schedule 3**.

[290] Centers for Disease Control and Prevention, Data Brief 294. Drug Overdose Deaths in the United States, 1999- 2016, available at https://www.cdc.gov/nchs/data/databriefs/db294_table.pdf#page=4

[291] Congressional Report at 49; *citing* U.S. Drug Enforcement Admin., *West Virginia 2007.*

> prescription drug overdoses in the United States has worsened over the last decade, and by 2008, drug overdose deaths (36,450) were approaching the number of deaths from motor vehicle crashes (39,973), the leading cause of injury death in the United States. Parallel trends in deaths and [prescription opioid] sales between 1999 and 2008, combined with continuing upward trends in ED visits, [prescription opioid] abuse treatment admissions, and OPR sales after 2008 suggest that the death rate also has increased since 2008. Preliminary 2009 death data are consistent with such an increase. These increases occurred despite numerous warnings and recommendations over the past decade for voluntary education of providers about more cautious use of [prescription opioids] (*16*)."[292]

- The United States Health and Human Services Division reported in 2015 that "the abuse of and addiction to opioids is a serious and challenging public health problem. Deaths from drug overdose have risen steadily over the past two decades and have become the leading cause of injury death in the United States" and "prescription drugs, especially opioid analgesics—a class of prescription drugs such as hydrocodone, oxycodone, morphine, and methadone used to treat both acute and chronic pain — have increasingly been implicated in drug overdose deaths [since 2005]."[293]

- In 2017, the International Narcotics Control Board found that in 2016, the United States consumed over 99% of the world's hydrocodone and almost 80% of the world's oxycodone.[294]

At each of these points in time, and numerous others,[295] Defendants had the opportunity to evaluate the public health and societal impact that the massive amounts of opioids they were supplying was having and to change its policies and procedures. Instead, the Defendants continued to engage in activities that exacerbated an already severe public health crisis in the United States and, acutely in the Cabell-Huntington Community today.

Internal documents, however, show a callous disregard for the devastation the pills were causing among Defendants and their business partners in the opioid industry and an attitude of shipping despite the consequences.

[292] Paulozzi LJ. (2010). *The epidemiology of drug overdoses in the United States*. Presented at Promis. Leg. Responses to the Epidemic of Prescr. Drug Overdoses in theU.S., Maimonides Med. Cent.Dep. Psychiatry, Dec. 2, Grand Rounds, Brooklyn.

[293] https://aspe.hhs.gov/basic-report/opioid-abuse-us-and-hhs-actions-address-opioid-drug-related-overdoses-and-deaths

[294] Int'l Narcotics Control Bd., Narcotic Drugs: Estimated World Requirements for 2018; Statistics for 2016, 36 (2017), available at https://www.incb.org/documents/Narcotic-Drugs/TechnicalPublications/2017/Narcotic_drugs_technical_publication_2017.pdf

[295] Defendants documents should numerous recognition that an "epidemic" was occurring as a result of the opioid pills they were supplying.

One Defendant, Amerisource Bergen's executives even joked about the epidemic, describing the residents of West Virginia "pillbillies" and crafting a jingle set to the tune of the Beverly Hillbillies mocking the epidemic of addiction in West Virginia.[296] One of Defendants' business partners, Mallinckrodt, who had received an email from a distributor, regarding shipments of oxycodone wrote Mallinckrodt saying: "Keep'em comin'! Flyin' out of here. It's like people are addicted to these things or something. Oh, wait, people are . . ." to which Mallinckrodt responded: "Just like Doritos keep eating. We'll make more."[297]

d. The Defendants continued to do business with admitted lawbreakers who had lied in promoting prescription opioids and who had been cited for breaking laws governing opioid distribution.

In 2003, the federal government issued a report detailing Purdue's improper marketing of OxyContin.[298] Had the Defendants ceased supplying OxyContin after the release of the report, as a prudent distributor of narcotics should have done, the Opioid Epidemic might have been brought to an early end and a strong message to deter other opioid manufacturers from improper marketing would have been sent. Instead, the Defendants chose to ignore Purdue's greed and recklessness and continued to do business with the company increase sales. Even after Purdue and other opioid manufacturers were criminally convicted, the Defendants continued to do business with Purdue, helped it promote its products and joined Purdue in an effort to preserve the status quo by deceiving regulators, policymakers, health professionals and the public. Defendants further continued to do business with retail and independent pharmacies who repeatedly violated the law designed to protect the public and lacked adequate systems to ensure that narcotics appropriately stayed in a "closed system."

1. Purdue

On May 10, 2007, The Purdue Frederick Company, Inc. pled guilty to felony misbranding of Oxycontin with the intent to defraud or mislead and agreed to pay over $600 million in criminal and civil penalties, fines and forfeitures.[299] In its plea agreement, Purdue stated "PURDUE is pleading guilty, as described above, because PURDUE is in fact guilty."[300] The news was widely publicized by media outfits all over the country.[301]

[296] ABDCMDL00569571.

[297] MNK-T1_0000559532.

[298] United States Governmental Accountability Office, Report to Congressional Requesters, "Prescription Drugs: Oxycontin Abuse and Diversion and Efforts to Address the Problem," GAO-04-110 (December 2003).

[299] Plea Agreement, Case 1:07-cr-00029-JPJ (W.D. Va.).

[300] *Id.* at p. 2.

[301] *See e.g.* https://www.nytimes.com/2007/05/10/business/11drug-web.html; https://www.reuters.com/article/us-oxycontin-misbranding/purdue-frederick-pleads-guilty-in-oxycontin-case-idUSWBT00695020070510; https://www.cnbc.com/id/18591525.

Instead of backing away from doing business with a convicted criminal who had put public health and safety at risk and caused death and addiction by lying about the risks of widespread use of their opioid products, Defendants actually worked to strength their relationship with Purdue in the years following Purdue's guilty plea, to advance their common purpose of having "no interruption in the supply chain" and to protect themselves from "over-zealous regulators."[302]

Just after Purdue pled guilty to felony offenses regarding its opioid products, Defendants began meeting with Purdue to address their next obstacle, the DEA's effort to increase enforcement of the distributors' compliance obligations. In 2008, the Defendants met with Purdue to discuss DEA's latest plans "to squeeze the wholesalers and distributors on 'pain clinics.'"[303] Purdue summarized the Defendants' representatives who met to discuss a coordinated strategy to combat the DEA as "men I consider personal friends of mine."[304]

Meetings with this known felon focused on "communication and cooperation,"[305] "collaborat[ion]…on issues about [Purdue] product(s),"[306] a "collaborative effort,"[307] "maximiz[ing] [their] shared objectives,"[308] and helping the opioid industry protect itself from "over-zealous regulators."[309] McKesson endorsed this collaborative effort in the years following Purdue's conviction and stated that "[it] was in 100% agreement with Purdue and . . . recognized

[302] PPLPC053000021255 at 256-259; PPLPC018000200323; PPLP004385367; PPLPC004000182848 at 848-49; ABDCMDL00364944; CAH_MDL2804_0087957; PPLP004474439; PPLP004474439-440; MCKMDL00536290; PPLPC053000039688; HDS_MDL_00086622; CAH_MDL2804_00851292; PPLPC021000249399; PPLPC019000346516-519; Exh. 256, PPLPC034000451465; PPLP004469304; PPLP004473046; PPLP004473318 at 319; PPLP004437208 at 209-215; PPLP004469394; PPLPC023000285327; PPLP004473227; PPLPC018000502666 at 667-670; PPLPC020000496773; MCKMDL00634412; PPLP004472303; PPLPC004000310913; ABDCMDL00301700; PPLP004473294 at 295-296; PPLPC020000558069; PPLPC022000513320-321; MCKMDL00575490 at 491-492; CAH_MDL2804_008795722.

[303] PPLPC018000200323.

[304] *Id.*

[305] PPLPC004000182848.

[306] CAH_MDL2804_00879572.

[307] PPLP004474439-440; MCKMDL00536290.

[308] MCKMDL00634412.

[309] CAH_MDL2804_00879572.

that this collaborative effort was the right thing to do."[310] As McKesson stated, "we ultimately protect ourselves."[311]

"Protecting themselves," meant that this time Defendants would team up with known criminals to break the law in a different way, this time through circumventing the protections designed to prevent oversupply and diversion. Internal documents show Purdue telling McKesson that "Joe Rannazzisi [of the DEA] is publicly stating that 'Manufacturers are now sending letters to their wholesale distributor consumers warning them of their due diligence obligations. . .,' our Purdue Team does not and will not operate in that manner."[312] Similarly, Purdue wrote to Cardinal stating that "[w]e should gang up on DEA."[313] Defendants did not reject Purdue's blatant proposals to break the law, they did not stop doing business with this repeated law breaker and they did not turn Purdue in to law enforcement. Instead, they embraced the plan of circumventing regulations and defying law enforcement, putting the public health and safety directly at risk to "protect themselves."

2. Cephalon

In 2008, Cephalon Inc. entered a criminal plea and paid $425 million in criminal and civil penalties to resolve claims that it marketed three drugs, including the opioid Actiq, for uses not approved by the Food and Drug Administration (FDA).[314] In short, Cephalon had taken its exceptionally potent transmucosal fentanyl product approved for use in treating breakthrough cancer pain in opioid tolerant patients and marketed the drug widely for unapproved uses.[315] The criminal investigation occurred after Cephalon's own employees turned the company in for its illegal practices.[316] In a public statement, the United States Department of Justice made clear that Cephalon's illegal conduct had put the public health at risk, stating "[t]hese are potentially harmful drugs that were being peddled as if they were, in the case of Actiq, actual lollipops instead of a potent pain medication intended for a specific class of patients. **This company subverted the very process put in place to protect the public from harm, and put patients' health at risk for nothing more than boosting its bottom line.**"[317]

[310] PPLP004474439-440; MCKMDL00536290.

[311] *Id.*

[312] MCKMDL00536290.

[313] CAH_MDL2804_00851292.

[314] https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html

[315] *Id.*

[316] *Id.*

[317] *Id.* (emphasis added)

Had the Defendants acted as prudent distributors of narcotics by refusing to do further business with Cephalon and Purdue after their criminal convictions and after it became known these the actions of these companies had led to addiction and loss of life. Instead of sending a message that improper and illegal promotion of narcotics will not be tolerated, the Defendants carried on with their criminally convicted business partners as if nothing had happened.

Undeterred, Cephalon promoted Fentora, its new transmucosal fentanyl product for unapproved uses, just as it did with Actiq. In 2009, it received a warning letter from the FDA that its materials for Fentora were deceptive because they broadened the indication for the drug beyond cancer patients with breakthrough pain.[318] And even after getting caught a second time for improper marketing of an exceptionally potent opioids, Defendants went on supplying Teva/Cephalon's opioid products.

3. Mallinckrodt

In 2017, Mallinckrodt reached an administrative settlement for $35 million with the DEA, acknowledging that: "at certain times under the Covered Time Period prior to January 1, 2012 [2008 through 2011], certain aspects of Mallinckrodt's system to monitor and detect suspicious orders did not meet the standards outlined in letters from the DEA Deputy Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007. The DEA had cited Mallinckrodt, alleging that it knew about "an epidemic increase in diversion of the controlled substance oxycodone, largely out of the state of Florida" and that the company "knew about the diversion and sold excessive amounts of the most highly abused forms of oxycodone, 30 mg and 15 mg tablets, placing them into a stream of commerce that would result in diversion."[319] The DEA also alleged that "even though Mallinckrodt knew of the pattern of excessive sales of its oxycodone feeding massive diversion, it continued to incentivize and supply these suspicious sales. Furthermore, the United States alleges that Mallinckrodt never notified the DEA of the suspicious orders in violation of the CSA."[320]

Mallinckrodt was one of Defendants' biggest customers.

4. Insys

Defendants also partnered with Insys to sell its opioid products. During this time, however, Defendants' business partner was engaged in criminal activity with respect to those products. On December 6, 2016, Insys founder and former Executive Chairman John Kapoor, Michael Babich, Alec Burlakoff, Richard Simon, Sunrise Lee, Joseph Rowan and Michael Gurry, all former executives and managers of Insys Therapeutics Inc., were charged by indictment by the United States Attorney's Office for the District of Massachusetts with conspiracy to commit racketeering, mail and wire fraud, and conspiracy to violate the anti-kickback law in relation to a

[318] NEED CITE

[319] *Administrative Memorandum of Agreement* between DEA and Mallinckrodt, July 10, 2017. https://www.justice.gov/usao-edmi/press-release/file/986026/download/.

[320] *Administrative Memorandum of Agreement* between DEA and Mallinckrodt, July 10, 2017.

nationwide conspiracy to bribe medical practitioners to unnecessarily prescribe a fentanyl-based pain medication and defraud payers of the medication, including insurers.[321] The indictment alleged that defendants conspired to bribe practitioners in various states, many of whom operated pain clinics, in order to get them to prescribe a fentanyl-based pain medication, called Subsys, a powerful narcotic intended to treat cancer patients suffering intense episodes of breakthrough pain. In exchange for bribes and kickbacks, the practitioners wrote large numbers of prescriptions for the patients, most of whom were not diagnosed with cancer.

The investigation of Insys would reveal that in their effort to push prescribing of the highest priced, highest dosage formulation of their fentanyl spray, Defendant McKesson, provided Insys with data from the transmucosal immediate-release fentanyl (TIRF) REMS program it administered.[322] The TIRF REMS data McKesson packaged for manufacturers of companies was valuable to them and much better than data available to drug makers from IQvia or anywhere else. Because McKesson's REMS data was real time and detailed. The McKesson data included information on prescribers, which drug and amount and dose, as well as patient identifiers that the Insys was able to match to patients they knew through doctors they were bribing. This was data that the companies should not have received but was incredibly useful for their sales team to implement a corrupt system of financial incentives to prescribers.

With the data provided by McKesson, Insys was able to implement an "effective dose campaign" that would question the doctors dosing of patients within hours of that prescription being written. Within 24 hours, a sales rep could be in a doctor's office questioning the dosing decision on the patient that had just been seen.

On May 2, 2019 Kapoor, Simon, Lee, Rowan, and Gurry were convicted by a federal jury of the RICO conspiracy charges.[323] Burlakoff and Babich has previously pled guilty. The defendants were sentenced to jail sentences ranging from 12 months to 6 months and were required to pay more than restitution of over $50,000,000.[324]

Retail Chain Pharmacy Partners

Defendants also continued their opioid business relationships with national retail pharmacy chains even after each had been cited for breaking the law and paid fines.

1. CVS

[321] Indictment.

[322] UNITED STATES OF AMERICA, Plaintiff, Criminal Action No. 16-CR-10343-ADB v. MICHAEL J. GURRY et al. TRANSCRIPT OF JURY TRIAL -- DAY 17, page 161.; https://www.mckesson.com/About-McKesson/Newsroom/Press-Releases/2012/RelayHealth--McKesson-Administer-First-Class-Wide-TIRF-REMS-Program/

[323] Verdict Form.

[324] https://www.justice.gov/usao-ma/victim-and-witness-assistance-program/united-states-v-michael-babich-alec-burlakoff-richard-simon-sunrise-lee-joseph-rowan-and

Between 2013 and 2017, CVS was repeatedly cited for egregious violations its of its responsibilities under the CSA and paid millions of dollars in fines to resolve those claims.[325] The numerous violations found by the DEA included:[326]

- Filling prescriptions for prescribers whose DEA registration numbers were not current or valid;
- Entering and maintaining CVS dispensing records, including prescription vial labels that identify a non-prescribing provider as the prescribing provider for certain prescriptions.
- Failure to maintain effective controls against the diversion of controlled substances
- Failure to timely detect and report suspicious orders of controlled substances
- Failure to keep complete and accurate records of Schedule II controlled substances
- Failed to report a robbery immediately to the DEA in violation 21 C.F.R. § 1301.76(b)
- Filled prescriptions for Schedule III controlled substances written by nurse practitioners who were not authorized under state law or by terms of their DEA registration to issue such prescriptions in violation of 21 U.S.C. § 842(a)(1) and 21 C.F.R. § 1306.03(a)(1);
- Entering, creating, or maintaining CVS dispensing records in which the DEA registration numbers of non-prescribing practitioners, were substituted for the DEA registration numbers of prescribing practitioners in violation of 21 U.S.C. § 842(a)(5) and 21 C.F.R. § 1306.24.
- Sending far too much hydrocodone to locations where the population could never legitimately warrant the supply
- Filling forged prescriptions for controlled substances – mostly addictive painkillers – more than 500 times between 2011 and 2014.
- Inadequately preventing and reporting thefts of hydrocodone

Defendants, however, continued to supply CVS with narcotics, including in the Cabell-Huntington Community.

2. Rite Aid

On January 11, 2009, Rite Aid entered into a $5 million settlement agreement with DEA. The DEA had alleged that: "At pharmacies in Kentucky and New York, Rite Aid knowingly filled prescriptions for controlled substances that were not issued for a legitimate medical purpose pursuant to a valid physician-patient relationship." Another allegation was that "the DEA conducted accountability audits of controlled substances at 25 of the 53 stores investigated to determine whether Rite Aid could properly account for Schedule II and III controlled substances purchased and dispensed. The results of the accountability audits revealed significant shortages

[325] *See* CVS-MDLT1-000060822-829; CVS-MDLT1-00060907-914; CVS-MDLT1-000060796-804; CVS-MDLT1-000099702-704; CVS-MDLT1-000060847-855; CVS-MDLT1-00060915-921; CVS-MDLT1-00008014-015; CVS-MDLT1- 000076135; ; CVS-MDLT1-000060805-811; United States District Attorney's Office, District of Massachusetts. (June 30, 2016) *CVS to Pay $3.5 Million to Resolve Allegations that Pharmacists Filled Fake Prescriptions* [Press Release]. Available at https://www.justice.gov/usao-ma/pr/cvs-pay-35-million-resolve-allegations-pharmacists-filled-fake-prescriptions (last visited March 19, 2019); CVS-MDLT1_000060830-838.

[326] *Id.*

or surpluses of the most highly abused drugs, including oxycodone and hydrocodone products, reflecting a pattern of non-compliance with the requirements of the CSA and federal regulations to prevent diversion of controlled substances in and around the communities of the Rite Aid pharmacies."[327]

Additionally, on March 9, 2017, Rite Aid entered into an $834,200 settlement agreement with DEA, after "certain Rite Aid pharmacies in Los Angeles dispensed and/or recorded controlled substances using a medical practitioner's incorrect or invalid DEA registration number. The investigation revealed the incorrect or invalid registration numbers were used at least 1,298 times as a result of Rite Aid's failure to adequately maintain its internal database. The settlement resolved allegations that Rite Aid pharmacies dispensed prescriptions for controlled substances written by a practitioner whose DEA registration number had been revoked by the DEA for cause."[328]

Defendants continued to do business with Rite Aid.

3. Walgreens

On June 11, 2013, Walgreens entered into a settlement with DEA in which it agreed to pay $80 million to resolve allegations that it failed to maintain effective controls against diversion of controlled substances and to detect and report suspicious orders.
Walgreens admitted the following:

> Walgreens acknowledges that suspicious order reporting for distribution to certain pharmacies did not meet the standards identified by DEA in three letters from DEA's Deputy Assistant Administrator, Office of Diversion Control sent to every registered manufacturer and distributor, including Walgreens, on September 27, 2006, February 7, 2007, and December 27, 2007. Furthermore, Walgreens acknowledges that certain Walgreens retail pharmacies did on some occasions dispense certain controlled substances in a manner not fully consistent with its compliance obligations under the CSA (21 U.S.C. §§ 801 et seq.) and its implementing regulations (21 C.F.R Part 1300 et seq.)."[329]

[327] Department of Justice. Rite Aid corporation and subsidiaries agree to pay $5 million in civil penalties to resolve violations in eight states of the Controlled Substances Act (press release). Washington, DC: United States Department of Justice, January 12, 2009. https://www.justice.gov/opa/pr/rite-aid-corporation-and-subsidiaries-agree-pay-5-million-civil-penalties-resolve-violations.

[328] Department of Justice. Rite Aid pays $834,200 settlement for alleged Controlled Substances Act violations in Los Angeles (press release). Los Angeles, CA: Drug Enforcement Administration, March 9, 2017. https://www.dea.gov/press-releases/2017/03/09/rite-aid-pays-834200-settlement-alleged-controlled-substances-act.

[329] *Settlement and Memorandum of Agreement* between Walgreens and DEA, June 11, 2013. https://www.wthr.com/sites/wthr.com/files/archive/WalgreensMOA.pdf.

The DEA had alleged that Walgreens sent 2.2 million, 2.2 million, 1.7 million, 1.4 million, 1.3 million, and 1.2 million to six pharmacies during a time when average retail pharmacy in the U.S. dispensed a total of 74,316 dosage units of oxycodone.[330] The DEA noted:

> "Perhaps even more significant than the enormous amount of oxycodone Respondent shipped to this store despite the information provided by the Chief of Police to its pharmacists and most senior leaders, is the fact that the dispensing records for both Oviedo Walgreens pharmacies show that on multiple occasions, they each dispensed additional prescriptions of commonly diverted narcotics to the same individuals who they knew had been previously arrested for drug offenses at their pharmacies. I find this to be a staggering disregard of Walgreens' obligations under the Controlled Substances Act."[331]

The DEA also stated that:

> "The available evidence suggests that [Walgreen's] abdication of its responsibilities as an individual registrant was at least facilitated by a push from Walgreens Corporate headquarters to increase oxycodone sales at its Florida retail pharmacies, all of which received their Schedule II controlled substances from [Walgreens]. I also note that during the relevant time herein, Walgreens had in effect compensation programs for pharmacy employees in which bonuses were based on the number of prescriptions filled at the pharmacy. This bonus program, combined with a concerted, corporate directed effort to increase oxycodone sales, served as an incentive for pharmacists and pharmacy technicians to ignore the 'red flags' of diversion presented by these prescriptions, many of which, in the proper exercise of the pharmacist's corresponding responsibility under 21 CFR § 1306.04(a), should have resulted in a refusal to fill."[332]

Despite Walgreen's admitted wrongdoing, the Defendants continued to supply Walgreens with narcotics, including in the Cabell-Huntington Community.

Independent West Virginia Pharmacies

Defendants practice with independent pharmacies was no different. Indeed, as the 2018 Congressional Report details, Defendants discovered egregious examples of criminal activity and diversion regarding local pharmacies, pharmacists and prescribers and either kept selling unchecked to parties that were acting recklessly and or criminally or stopped shipments for a

[330] DEA. *Order to Show Cause and Immediate Suspension of Registration*. In the matter of Walgreen Co., September 13, 2012. Pl. 3924. www.dea.gov/divisions/mia/2013/mia061113_appendix.pdf.

[331] *Id.*, p. 8.

[332] *Id.*, p. 6.

brief period and then resumed selling without meaningful evidence that conditions had improved.[333]

Defendants' practices were no different in Huntington. For example, as detailed in Section 5.b. above, and in the Expert Report of James Rafalski, AmerisourceBergen continued selling to the Safescript Pharmacy, despite repeated evidence that criminal activity and obvious diversion was going on at the pharmacy. Additionally, as detailed above, local prescribers who were ultimately criminal prosecuted went completely undetected by Defendants.

Had the Defendants operated as prudent distributors of narcotic drugs they would not have turned a blind eye to the overt wrongdoing and criminal behavior of their partners in the supply chain. As the largest distributors of pharmaceutical products in the country, had the Defendants made clear to the industry that improper marketing and retailing of narcotics would not be tolerated, wrongdoing by their business partners would have ceased, millions of cases of opioid addiction might have been prevented and thousands of needless deaths prevented.

e. The Defendants repeatedly and blatantly broke the law designed to control oversupply and prevent diversion.

To be granted the privilege of selling dangerous scheduled narcotics, each distributor must comply with the Controlled Substances Act ("CSA"). *See* 21 U.S.C. §§ 801–971 (2006); 21 C.F.R. §§ 1300–1321 (2009).[334] As McKesson recognized in one internal presentation, distributors have "great power" within this system, but "with great power comes great responsibility."[335] Under the CSA, each distributor owes a duty to protect the public health and safety by maintaining ***effective*** controls against diversion of prescription opiates into the illicit market. 21 U.S.C.A. § 823(b)(1) [1970](emphasis added). The regulations specifically require all distributors to report suspicious orders of controlled substances, in addition to the statutory responsibility to exercise due diligence to avoid filling suspicious orders. In addition, federal regulations impose additional security control requirements on nonpractitioner DEA registrants, such as distributors including, but not limited to:

> "The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division of the Administration in his region of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[336]

[333] Congressional Report at 130-171 and documents cited therein.

[334] I have been provided the relevant portions of the Controlled Substances Act ("CSA") and its implementing regulations create restrictions on the distribution of controlled substances. *See* 21 U.S.C. §§ 801–971 (2006); 21 C.F.R. §§ 1300–1321 (2009). They are listed in Schedule 3, attached to this Report.

[335] MCK-AGMS-006-0000916-917.

[336] 21 C.F.R. § 1301.74(b).

As summarized by McKesson in internal documents, the CSA is designed to protect public health and safety and therefore compliance by all registrants in the closed system of distribution of narcotics is critical to protecting that public health and safety."[337] The CSA was designed to protect the public health by providing for a closed system of drug distribution, in which all legitimate handlers of controlled substances must obtain a DEA registration, and as a condition of maintaining such registration, must take reasonable steps to ensure their registration is not being used as a source of diversion. As summarized in Defendants internal documents, compliance impacts diversion and the "checks and balances created by the Controlled Substances Act work."[338] Indeed, as recognized in McKesson documents, major diversion schemes cannot exist without sustained sources of supply.[339]

It was utterly foreseeable, and Defendants recognized it in internal documents, that communities would be harmed if they failed to comply with their important obligations under the CSA.[340] Major diversion was preventable by Defendants, the primary sources of supply.[341] As the wave of pills that the Defendants were selling swept over the United States and, overwhelmed West Virginia, however, it became clear that Defendants were not meeting these obligations and that oversupply, lack of knowledge about where prescription opioids were going, and diversion was rampant.

With its limited and often severely inadequate resources, the DEA tried to ensure that Defendants and the opioid industry complied with the legal obligations of the CSA, an effort later titled "the Distributor Initiative."[342] The DEA's first step was to make clear in writing and through in person meetings with each company, what the law that had been in effect since 1970 required, so no company could claim ignorance.[343] AmerisourceBergen, Cardinal, H.D. Smith and McKesson each had one-on-one meetings with DEA as part of this initiative.[344] In addition, during 2006 and 2007, the DEA sent a series of three letters to DEA-registered distributors,

[337] MCK-AGMS-006-0000887 (The CSA "creates checks and balances between registrants to protect the public health and safety.")

[338] MCK-AGMS-006-0000925.

[339] MCK-AGMS-006-0000925.

[340] *See* Chris Zimmerman [AmerisourceBergen] Deposition (August 3, 2018) at 104:14-17.

[341] *See e.g.* MCK-AGMS-006-0000892; McKesson's 30(b)(6) representative confirmed that opioids "come ultimately from the manufacturer, distributor, pharmacy", and "[w]ithout sustained sources of supply, major diversion schemes wither away". *See* July 31, 2018 30(b)(6) deposition of McKesson through Nate Hartle at 298:18-299:17.

[342] Congressional Report at 31-33.

[343] *Id.*

[344] *Id; see also* US-DEA-00000352; US-DEA-00000369; US-DEA-00000371; US-DEA-00000147; US-DEA-00000144.

outlining their legal obligations to conduct due diligence and report suspicious orders.[345] Beginning in 2007, the DEA held five separate national conferences, three of which were exclusively for distributors, where the agency "reviewed the distributors legal responsibilities under the CSA and provided updates on DEA's areas of concern and current trends regarding controlled substance diversion."[346]

McKesson's internal documents summarized all of the advance warnings to the opioid distributors about exactly what their obligations to prevent diversion were and the expectations for following them, including:[347]

- The Distributor Initiative
- Reminder letters sent to industry
- Industry conferences were the message of compliance was communicated
- Meetings with the HDMA and industry representatives
- Education for downstream participants
- Congressional testimony

Despite these efforts, however, Defendants were not taking their compliance requirements seriously. Therefore, beginning in 2007 and 2008, the DEA took enforcement action for violations of the law against the Defendants. Time and again between 2007 and 2017, Defendants were cited by the DEA for violating the CSA and failing to comply with its requirements to protect the public health, including:

1. April 24, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the AmerisourceBergen Orlando, Florida distribution center alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement and release agreement with the DEA related to the allegations made by the agency.[348]

2. November 29, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Auburn, Washington Distribution Center which

[345] *Id.; see also* CAH_MDL_PRIORPROD_DEA07_00837645; CAH_MDL_PRIORPROD_DEA07_01053067; ABDCMDL00378493; MCKMDL00478906; MCKMDL00478910.

[346] Congressional Report at 33.

[347] MCK-AGMS-006-0000907.

[348] AmerisourceBergen Corporation, *AmerisourceBergen Signs Agreement with DEA Leading to Reinstatement of its Orlando Distribution Center's Suspended License to Distribute Controlled Substances*, June 22, 2007, available at http://investor.amerisourcebergen.com/news-releases/news-release-details/amerisourcebergen-signs-agreement-dea-leading-reinstatement-its (last visited March 11, 2019).

suspended their DEA registration for failure to maintain effective controls against diversion of hydrocodone.[349]

3. December 7, 2007, DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center for failure to maintain effective controls against diversion of hydrocodone.[350]

4. December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Swedesboro, New Jersey Distribution Center for failure to maintain effective controls against diversion of hydrocodone.[351]

5. January 30, 2008, the DEA issued an Order to Show Cause against the Cardinal Health Stafford, Texas Distribution Center for failure to maintain effective controls against diversion of hydrocodone. Cardinal agreed to suspend shipping any controlled substances from the location pending a resolution with the DEA.[352]

6. May 2, 2008, McKesson Corporation agree to pay a $13 million civil penalty and entered into an Administrative MOA with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program.[353]

7. On September 30, 2008, Cardinal Health agreed to pay a $34 million civil penalty and entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement (MOA) with the DEA related to its Auburn Facility, Lakeland Facility,

[349] Cardinal Health, Press Release, *Cardinal Health Receives DEA Order to Temporarily Cease Distribution of Controlled Substances from Auburn Wash. Facility*, November 29, 2007, available at https://ir.cardinalhealth.com/news/press-release-details/2007/Cardinal-Health-Receives-DEA-Order-to-Temporarily-Cease-Distribution-of-Controlled-Substances-from-Auburn-Wash-Facility/default.aspx

[350] Cardinal Health press release, *Cardinal Health to Cease Distribution of Controlled Substances from Florida Facility*, December 7, 2007, available at https://cardinalhealth.mediaroom.com/newsreleasearchive?item=122500.

Drug Topics, *DEA hits third Cardinal Health distribution center*, December 21, 2007, available at https://www.drugtopics.com/pharmacy/dea-hits-third-cardinal-health-distribution-center.

[352] Drug Topics, *Cardinal caught between DEA and pharmacies over diversion control*, April 14, 2008, available at https://www.drugtopics.com/community-practice/cardinal-caught-between-dea-and-pharmacies-over-diversion-control.

[353] May 2, 2008 Settlement and Release Agreement and Administrative Memorandum of Agreement between DEA and McKesson Corporation, available at https://www.dea.gov/sites/default/files/2018-06/Pharmaceutical%20Agreements%20-%20McKesson%20-%202008_0.pdf.

Swedesboro Facility and Stafford Facility. The MOA also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances.[354]

8. February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center for failure to maintain effective controls against diversion of oxycodone.[355]

9. March 7, 2012, Memorandum of Opinion [Doc. 32] from the United States District Court for the District of Columbia, *Cardinal Health, Inc., vs. Eric H. Holder, Jr.*, Civil Action No. 12-185 (RBW), denying Cardinal's challenge of the DEA's Order to Show Cause and Immediate Suspension of Registration of Cardinal's Lakeland Distribution Center.[356]

10. May 14, 2012, Cardinal Health entered into an Administrative MOA with the DEA, which, among other things, stipulated that its compliance with the terms of the 2008 MOA was inadequate in certain respects and that its Lakeland, Florida Distribution Center's DEA registration would be suspended for two years.[357]

11. December 23, 2016, Cardinal Health agreed to pay a $34 million civil penalty to the DEA to resolve allegations that it failed to report suspicious orders and meet its obligation under the CSA in Florida, Maryland, New York, and Washington.[358]

12. January 5, 2017, McKesson Corporation entered into an Administrative MOA with the DEA wherein it agreed to pay a $150 million civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora, Colorado; Aurora, Illinois; Delran, New Jersey; LaCrosse, Wisconsin; Lakeland, Florida; Landover, Maryland; La Vista, Nebraska; Livonia, Michigan; Methuen, Massachusetts;

[354] United States Attorney's Office press release, *Cardinal Health Inc., Agrees to Pay $34 Million to Settle Claims That It Failed to Report Suspicious Sales of Widely-Abused Controlled Substances*, October 2, 2008. Available at https://www.justice.gov/archive/usao/co/news/2008/October08/10_2_08.html.

[355] 2012 Administrative Memorandum of Agreement entered into between DEA and Cardinal Health, CAH_MDL2804_02465982.

[356] Copy of Order available at https://www.govinfo.gov/content/pkg/USCOURTS-dcd-1_12-cv-00185/pdf/USCOURTS-dcd-1_12-cv-00185-0.pdf (last visited March 19, 2019).

[357] 2012 Administrative Memorandum of Agreement entered into between DEA and Cardinal Health, CAH_MDL2804_02465982.

[358] United States Attorney's Office, Middle District of Florida. (December 23, 2016) *United States Reaches $34 Million Settlement with Cardinal Health for Civil Penalties Under the Controlled Substances Act* [Press Release]. Available at https://www.justice.gov/usao-mdfl/pr/united-states-reaches-34-million-settlement-cardinal-health-civil-penalties-under (last visited March 19, 2019).

> Santa Fe Springs, California; Washington Courthouse, Ohio; and West Sacramento, California.[359]

Each time the DEA caught and cited the Defendants, however, the Defendants did not take it as an opportunity to increase safety and compliance with the CSA, but rather continued business as usual. In fact, numerous internal documents evidence how Defendants made conscious decisions to ignore the law. For example, Cardinal Health employees stated in 2013 that they did not report suspicious orders to the DEA because there is "no upside.."[360] McKesson instructed its employees not to use the word "suspicious" so that the company could circumvent its obligations as follows:[361]

> With the recent fines and ongoing attention being paid to this issue, it is quite possible that wholesalers will be under scrutiny for quite some time. All communications regarding controlled substances will therefore be subject to subpoena and discovery. . . . Refrain from using the word 'suspicious' in communications. Once we deem an order and/or customer suspicious, McKesson is required to act. This means all controlled substances sales to that customer must cease and the DEA must be notified.

Indeed, as summarized in Defendants' internal documents, the incentive to break the law is monetary.[362] Compared to Defendants annual revenue, any of the fines or penalties were a mere drop in the bucket and a simple cost of doing business.

Each time, the Defendants simply agreed to a relatively modest monetary fine, promised to do better and went right on increasing demand and selling without restraint. For example, just after agreeing to pay its $13.8 million fine in 2008, McKesson reassured its pharmacy customers that its new program regarding suspicious order blocking "address[ed] the DEA's requirements to ensure controlled substances are used in the way they were intended," but that **"it also ensures that you as a McKesson customer can continue with business as usual."**[363] In 2017, McKesson was yet again undeterred by its most recent $150 million dollar fine. Indeed, two

[359] United States Department of Justice. (January 17, 2017) *McKesson Agrees to Pay record $150 Million settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs* [Press Release]. Available at https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders (last visited March 19, 2019).

[360] MCKMDL00545341 (emphasis added).

[361] MCKMDL00634271 (May 21, 2008 internal email advising employees to "Refrain from using the word 'suspicious' in communications" in the context of McKesson's controlled substance monitoring program (CSMP)).

[362] ABDCMDL00158927 (*Diversion Issues*, PowerPoint).

[363] MCKMDL00543610 at 613 (emphasis added).

weeks after its fine, McKesson reassured pharmacy customers that it would be "**business as usual from a threshold perspective**."[364]

Despite these warnings by the DEA, a 2018 Congressional investigation found that Defendants had continued to do business as usual, "the distributors continued to ship large volumes of opioids into West Virginia.[365] According to the Congressional report aptly titled "*Warning Signs, Ignored: Opioid Distribution and Enforcement Concerns in West Virginia,"* ("the Congressional Report" or "the Report") Defendants AmerisourceBergen, Cardinal Health, and McKesson, sent more than 900 million doses of hydrocodone and oxycodone to West Virginia between 2005 and 2016, where the average population hovered above 1.8 million people.[366] Specifically, the report found that between 2005 and 2016:[367]

- Cardinal Health distributed more than 366 million doses of hydrocodone and oxycodone to West Virginia pharmacies.

- McKesson supplied 299.87 million doses of hydrocodone and oxycodone to West Virginia pharmacies.

- AmerisourceBergen distributed 248.16 million doses of hydrocodone and oxycodone to West Virginia pharmacies.

"According to DEA analysis of market data, the hydrocodone disbursements to some pharmacies were as many as six times higher than the annual amount an average rural West Virginia pharmacy received."[368] Additionally, "[a]t the same time large amounts of opioids were being supplied to West Virginia, the DEA had data demonstrating the increasing problem with controlled substance diversion in the state."[369] The Congressional Committee found that this extraordinary volume of shipments in West Virginia was due in part to a "a series of breakdowns" in the Defendants systems that were required to check oversupply and prevent diversion including:[370]

- "Instances of insufficient due diligence by distributors."

[364] MCKMDL00418094 (emphasis added).

[365] Congressional Report at 6.

[366] *Id.*; *see also,* https://www.opendatanetwork.com/entity/0400000US54/West_Virginia/demographics.population.count?year=2018

[367] Congressional Report at 6.

[368] *Id.*

[369] *Id.*

[370] Congressional Report at 6-7.

- "Cases where data submitted by a new customer was not critically analyzed to identify any red flags of controlled substance diversion."

- "[P]otential red flags regarding a pharmacy's prescribing physicians that raised concerns about possible diversion were not questioned."

- "Instances where there were failures to monitor the volume of controlled substances sold to customers."

- "Thresholds [to track suspicious orders] were assigned arbitrarily, and not effective."

- "Instances in which distributors set thresholds but failed to enforce them."

- Instances in which distributors "assigned artificially high hydrocodone threshold limits with little to no documented justification or continued to raise threshold levels without thoroughly investigating or documenting the justifications presented by a customer pharmacy."

"Despite efforts by DEA to educate distributors about their responsibility to report suspicious orders, the companies reviewed by the Committee [including Defendants] failed to address suspicious order monitoring in critical ways" including:[371]

  - "Rather than reporting individual suspicious orders as they were identified, some distributors reported a variety of other types information to DEA over the years. This information included excessive orders encompassing drug shipments that had already been shipped, and suspicious customers such as pharmacies with which distributors had terminated business relationships. Neither of these types of reports informed DEA about suspicious orders in real-time nor did they guarantee the suspicious orders reported to DEA were also blocked by the distributors."

  - "One distributor lacked any formal order monitoring program. Rather, the distributor's employees relied on subjective criteria to identify orders it considered suspicious."

  - "Instances in which distributors appeared to turn a blind eye to red flags of possible drug diversion."

  - Instances in which "despite available information, distributors, at times, took only minimal steps to investigate possible warning signs of diversion and continued to ship controlled substances to suspect pharmacies."

[371] Congressional Report at 6-7.

- "In several cases, distributors either failed to fully investigate potentially troubling information they obtained from customer pharmacies or willfully ignored it."

The Committee concluded that "the extraordinary volume and pattern of opioid shipments, such as those sent to pharmacies in small West Virginia towns, were in the words, 'red flags of diversion'" and that distributors were "sending volumes of controlled substances to small town pharmacies that far exceeded what could be considered reasonable to meet the legitimate medical needs of area residents."[372] The Committee "identified failings in various aspects of [Defendants'] compliance programs or the implementation thereof. These included inadequate new customer due diligence efforts, poor implementation—or lack thereof—of thresholds capping the distribution of controlled substances, and suspicious order reporting, which resulted in continued shipments by the distributors to certain pharmacies despite clear red flags of diversion."[373] The Committee found that:[374]

> Distributors also at times shipped millions of opioid pills to small-town pharmacies with very little corresponding due diligence. In other instances, distributors had in their possession due diligence materials that should have prompted them to conduct independent investigations of certain pharmacy customers or required them to more frequently report suspicious orders to DEA. The Committee's investigation found, however, that distributors continued to ship opioids to these pharmacies for months and, in some cases, even years.

The Congressional Committee also made the following specific findings about Defendants' conduct in West Virginia noting that "distributors can obtain dispensing data from pharmacies that show the total volume of controlled substances dispensed by a pharmacy, including the method of payment and physician associated with each prescription:"[375] With this information at their disposal, however, the Congressional Committee cited how each Defendant committed egregious violations of compliance obligations at pharmacies in West Virginia, utterly failed to meeting their obligations under the CSA, and took actions that no reasonable distributor interested in protecting the public health and safety in West Virginia would take.[376]

As prescription opioids flowed into West Virginia communities at levels that could never be considered clinically warranted for the population, the Congressional Report found that "McKesson did not submit suspicious order reports to the DEA regarding orders placed by West

[372] Congressional Report at 100.

[373] Congressional Report at 105.

[374] Congressional Report at 106.

[375] Congressional Report at 112.

[376] Congressional Report at 12-32.

Virginia pharmacies until August 1, 2013."[377] "Cardinal did not have a consolidated suspicious order reporting system in place until 2012, was unable to produce comprehensive suspicious order reports regarding West Virginia pharmacies prior to 2012 and was unable to provide comprehensive data prior to 2012 demonstrating compliance with these reporting policies in West Virginia."[378] "Prior to July 2007, AmerisourceBergen mailed copies of suspicious order reports to the DEA on a monthly basis but did not block any orders deemed suspicious."[379] "The number of suspicious order reports regarding West Virginia pharmacies that AmerisourceBergen submitted to DEA and blocked from shipment ranged from a high of 792 orders in 2013 to a low of three orders in 2016."[380]

According to the Congressional Committee, "[t]hese failures raise substantial concern given that DEA has said existing knowledge of a geographic area's problem with controlled substance abuse is a factor that distributors should take into account when evaluating customers."[381] "West Virginia has had the highest drug overdose rate in the country—meaning distributors should have been particularly attuned to any red flags encountered when conducting due diligence on pharmacies in the state."[382] "Taken altogether, the Committee's report outlines a series of missteps and missed opportunities that contributed to the worsening of the opioid epidemic in West Virginia."[383]

I agree with the Committee's conclusion, although I would add that the Defendants actions outlined therein are not only "missteps," but were reckless, exhibit a total disregard for the public health and safety of the communities in West Virginia and were a substantial factor in causing the Opioid Epidemic in West Virginia and in the Cabell-Huntington Community.

Additionally, I have reviewed the Expert Report of James Rafalski.[384] Mr. Rafalski cites numerous failures in compliance with Defendants obligations under state and federal law, that occurred in the Cabell Huntington Community.[385] Specifically, the report cites a failure by each of the Defendants to maintain effective systems to prevent diversion and identifies additional

[377] Congressional Report at 16.

[378] *Id.*

[379] *Id.* at 17.

[380] Congressional Report at 16-17.

[381] Congressional Report at 7.

[382] *Id.*

[383] Congressional Report at 9.

[384] Expert Report of James Rafalski, dated August 3, 2020.

[385] *Id.*

violations of state and federal law committed by the Defendants.[386] As detailed in the Expert Report of Craig McCann, Ph.D., this was all happening at a time when Defendants were supplying a staggering amount of opioids into West Virginia, the Cabell-Huntington Community and the surround areas.[387] The Expert Reports of Mr. Rafalski and Dr. McCann additionally form the basis for my opinions contained in this section of my Report.

As Defendants themselves recognize in internal documents, failing to comply with CSA obligations designed to protect the public health and safety puts the public at a direct and unreasonable risk.[388] It is my professional opinion that this blatant disregard for their obligations under state and federal law, and the utter failure to correct their unsafe and illegal behavior when it was repeatedly cited by federal authorities, was a significant contributing factor in producing the Opioid Epidemic we see today.

f. The Defendants misrepresented the quality of their anti-diversion programs to keep regulatory and public scrutiny at bay and continue selling unchecked.

During the time Defendants were repeatedly breaking the law, blatantly failing to comply with their CSA obligations, recklessly flooding West Virginia with dangerous prescription opioids, and utterly failing to prevent diversion, each falsely represented the robust nature of their anti-diversion programs, their commitment to preventing diversion and their commitment to protecting public health and safety by preventing diversion. Indeed, at the time Defendants were assuring the public, regulators and the government that they took their compliance obligations seriously, that they had adequate systems in place to prevent diversion and that they were "industry leaders" in diversion protection they were being cited by the government for breaking the law, for their the woefully inadequate systems to prevent diversion and putting the public directly in harm's way. These misrepresentations put public health and safety at risk, in that they were designed to impede meaningful safety measures that could have helped prevent diversion and protect the public health and safety.

AmerisourceBergen

AmerisourceBergen has repeatedly stated, falsely, that it maintains an effective anti-diversion program. After its Orlando DC was suspended by the DEA in 2007 for failing to maintain effective controls against diversion, AmerisourceBergen pledged to improve its program.[389]

[386] *Id.* at 23-31, 40-42, 47-122.

[387] Expert Report of Craig McCann, Ph.D., dated August 3, 2020.

[388] *See e.g.*, MCK-AGMS-006-0000880.

[389] *See* ABDCMDL00279854 (2007 AmerisourceBergen settlement with DEA).

Amerisource then put out a public statement defending itself and casting doubt on the DEA's decision stating: [390]

> Historically, AmerisourceBergen has proactively cooperated with the DEA in preventing diversion of hydrocodone and other controlled substances and will fully cooperate with the agency in resolving the temporary suspension. The Company has a diversion program and a DEA-approved suspicious-order monitoring program in place to identify customers who are suspected of inappropriately selling products sold to them by AmerisourceBergen. All of the Orlando Distribution Center's DEA audits, the most recent within the last year, were passed with no deficiencies found.

AmerisourceBergen also represented to pharmacy customers in 2014 that it was an "industry leader" in preventing diversion and abuse, committed to ensuring "the safety of the pharmaceutical supply chain."[391] Nonetheless, in the same brochure, Amerisource communicated to pharmacies that it was willing to increase thresholds and work to minimize the impact of compliance requirements on customers' business.

Amerisource Chairman and CEO Steve Collis told Congress in 2018 that Amerisource has "worked with the DEA to enhance the system in 1998, and again in 2007, and [has] continually reviewed and improved [the anti-diversion program], including a comprehensive 2015 revision to build on current data, respond to trends in prescription drug abuse, and adopt improved technological capabilities, including data-driven analytical tools." (5/8/2018 Collis statement to Subcommittee on Oversight and Investigations Committee on Energy and Commerce).[392]

AmerisourceBergen also made false statements in response to regulators' questions about the effectiveness of the anti-diversion program. Specifically, the Ohio Board of Pharmacy asked Amerisource why it failed to report any suspicious orders during a period after April of 2016, and Amerisource replied that enhancements to the Order Monitoring Program and its "advanced analytics" were responsible for the sharp drop in the number of suspicious orders that were reported.[393] Amerisource also claimed that "red flag analytical reporting" improved its ability to "recognize and prevent potential diversion by our customers prior to their placing" suspicious orders.[394]

> As fully outlined in the Sections above and in the 2018 Congressional Report, these statements are not accurate. Further, at the time Amerisource was touting its anti-diversion systems publicly internal documents show it was being advised by consultants

[390] ABDCMDL00400594 (4/24/07 news release).

[391] ABDCMDL00360399 (OMP and Diversion Control brochure to pharmacy customers).

[392] https://docs.house.gov/meetings/IF/IF02/20180508/108260/HHRG-115-IF02-Wstate-CollisS-20180508.pdf

[393] ABDCMDL00354657 (email chain with Ohio Board of Pharmacy).

[394] *Id.*

that its systems were woefully inadequate.[395] Indeed, in 2015 ABDC's consultants reviewing ABDC's anti-diversion systems reported 40 adverse findings to Amerisource, including a lack of resources, a lack of formal training, excess workloads, and administrative demands, as well as inconsistent policies and communications.[396]

Cardinal Health

Cardinal has also repeatedly touted the strength of its anti-diversion practices and purported anti-diversion monitoring programs, despite multiple punitive actions against it by the DEA related to Cardinal's SOM failures, and Cardinal's own knowledge that it was skirting DEA requirements. In 2008, following numerous failures to adequately monitor and report suspicious orders and prevent diversion at its facilities, the DEA suspended three of Cardinal's distribution facilities and fined it $34 million. In its 2008 agreement with the DEA, Cardinal pledged to "maintain a compliance program designed to detect and prevent diversion of controlled substances," report suspicious orders to the DEA, file monthly reports with the DEA and "cooperate with the government in any investigation."[397]

In February 2012, Cardinal publicly asserted the strength of its anti-diversion program, stating that "Cardinal Health has designed and implemented a comprehensive system to detect and report suspicious orders . . . and prevent the diversion of controlled substances," "Cardinal Health has continuously improved its anti-diversion program," and that it "goes to great lengths to seek to prevent potential diversion of the controlled substances it sells to DEA-registered pharmacies."[398] However, Cardinal's representations were demonstrated to be false – just a few months later, in May 2012, the DEA suspended Cardinal's Lakeland, Florida facility for two years.[399] In the settlement agreement, Cardinal admitted that its due diligence efforts and compliance with the 2008 settlement agreement were "inadequate."[400]

Cardinal knew that it was not complying with the DEA's anti-diversion requirements all along. In fact, in 2013, at an industry conference Cardinal told its peers it does not report suspicious opioid orders because there is "no upside."[401]

Nonetheless, Cardinal continued to publicly promote its anti-diversion program. In 2016, after agreeing to pay yet another fine to DEA (this time for $44 million) for failure to maintain an

[395] ABDCMDL00250024 (8/17/15 FTI Findings Matrix); ABDCMDL00253869.

[396] ABDCMDL00250024 (8/17/15 FTI Findings Matrix)

[397] CAH_MDL_PRIORPROD_DEA12_00014414 (2008 Administrative Memorandum of Agreement).

[398] CAH_DEPO_MONE_OH_0000285 pp. 1-5 (2/3/2012 Declaration of Michael Mone, Cardinal's VP for Supply Chain Integrity).

[399] CAH_MDL2804_02149723 (DEA-Cardinal Administrative Memorandum of Agreement, May 2012).

[400] *Id.*

[401] MCKMDL00545341-342 (3/11/2013 email from W. de Guiterrez-Mahoney to D. Walker, et al.).

effective anti-diversion program, Cardinal stated as follows: "Cardinal Health employs a large organization dedicated to maintaining and continuously improving a sophisticated anti-diversion program that includes advanced analytics, technology, and the deployment of teams of anti-diversion specialists and investigators embedded within our supply chain."[402] Cardinal's repeated representations about its anti-diversion program are demonstrably false, and Cardinal has known it for years.

McKesson

McKesson made numerous misrepresentations to the DEA and the public that it was complying with its duties under the law to stop abuse and diversion of opioids. For instance, in a 1/18/2006 letter to DEA's Joseph Rannazzisi, McKesson's EVP and Group President Paul Julian stated: "let me assure you and DEA that McKesson is committed to a compliance program that ensures the safe distribution of health care products, especially controlled substances."[403] But DEA continued to find multiple flaws in McKesson's anti-diversion programs, resulting in a settlement and fine of $13.25 million in 2008.[404] This settlement required McKesson to substantially revamp its programs, including the imposition of strict threshold limits on pharmacies' purchases.[405]

McKesson publicly represented as part of the 2008 settlement that it would implement a program to "enhance its monitoring" to detect and prevent diversion: "The security of the nation's pharmaceutical supply chain is one of McKesson's highest priorities . . . McKesson continually seeks ways to enhance the efficiency and safety of pharmaceutical supply chain."[406]

However, once again, McKesson's representations were demonstrably false - in 2017, the DEA imposed a $150 million fine/settlement on McKesson.[407] The 2017 settlement agreement stated that "McKesson failed to follow the policies and procedures set forth in the McKesson CSMP to detect and disclose suspicious orders of controlled substances."[408] Moreover, McKesson acknowledged that its compliance failures leading to the 2017 settlement were of the same type

[402] CAH_MDL2804_03388866 (12/23/2016 news release, "Cardinal Health Announces Civil Settlement with DOJ").

[403] MCKMDL00571361.

[404] MCKMDL00332932 (Settlement and Release Agreement dated 5/2/2008).

[405] *Id.*

[406] *See McKesson Announces Settlement with DEA, Press Release.* Businesswire. (May 2, 2008), available at, https://www.businesswire.com/news/home/20080502005690/en/McKesson-Announces-Settlement-DEA.

[407] MCKMDL00355349 (1/5/2017 Administrative Memorandum of Agreement).

[408] *Id.*

that led to the 2008 settlement, and that despite the specific requirements of the 2008 settlement, McKesson had failed to take action to prevent the problems from reoccurring.[409]

McKesson knew all along that its representations about improvements to its anti-diversion program were false. For example, in 2008 during the initial rollout of the new Controlled Substances Monitoring Program, McKesson's Pharmacy Program Guide reassured its pharmacies that despite new DEA requirements such as thresholds, "you as a McKesson customer can continue with business as usual."[410] Moreover, in 2011, McKesson instructed its employees to skirt DEA requirements by avoiding use of the word "suspicious" in customer communications because "[o]nce McKesson deems an order and/or customer suspicious, McKesson is required to act. This means all controlled substances sales to that customer must cease, and the DEA must be notified."[411] In other words, McKesson knowingly undercut its own public statements about an improved anti-diversion program.

McKesson continues to make similar deceptive public statements about its anti-diversion activity. It claims to have "teams, processes and technologies dedicated to preventing diversion" and to be "committed to maintaining . . . strong programs designed to detect and prevent opioid diversion within the pharmaceutical supply chain."[412]

As demonstrated repeatedly over the years, these representations are clearly false.

HDA Misinformation regarding Distributors anti-diversion programs

Not only did distributors directly misrepresent their anti-diversion efforts, but they also did so through the HDA. These misrepresentations included statements that Defendants were implementing suspicious order monitoring programs reasonably designed to identify and prevent opioid shipments that were at high risk of diversion.[413] For example, HDA developed what was "supposed to be a 'best practices' model for dealing with 'suspicious orders,'" called the Industry Compliance Guidelines (ICGs).[414] The HDA then used the ICG to assure the DEA that HDA would promote the ICGs to its members and to "allied trade associations," such as

[409] *Id.* at 3.

[410] MCKMDL00543612 (4/4/2008 Program Guide; emphasis added).

[411] MCKMDL00000021 at p. 19 (January 2011 McKesson Operations Manual for Pharma Distribution).

[412] *See* McKesson Website, "Opioid Abuse – Fighting the Epidemic." *available at* https://www.mckesson.com/About-McKesson/Fighting-Opioid-Abuse/ ; *see also* MCKMDL01387750 (Chairman/CEO John Hammergren's 5/8/2018 written testimony before House subcommittee claiming that McKesson has "significantly enhanced our monitoring systems and procedures, so that we can quickly identify and block suspicious orders, and cut off bad actors' access to controlled substances.").

[413] *See*, e.g., HDA_MDL_000131158 (2013 "Infographic" touting distributors' "safe and efficient distribution" of healthcare products, "sophisticated" processes and alerts to the DEA of suspicious orders).

[414] HDA_MDL_000157898.

"NACDS" and "manufacturer associations (Pharmaceutical Research and Manufacturers Association – PhRMA and the Generic Pharmaceutical Association --GPHA)" such that the ICGs would serve as an industry-wide standard.[415] HDA even told the DEA that it hoped "that DEA would find the guidelines acceptable as a voluntary 'consent decree,'" and that with the enforcement of the ICG that Defendants "intended to be part of the solution rather than the problem."[416] When making these representations, HDA never mentioned it had no power to compel its members to adopt the guidelines and had never asked it members to do so.[417] After DEA tried to use the Guidelines in enforcement actions only to hear that the companies had not committed to following them, HDA admitted that the Guidelines were "never intended to constitute a 'standard'"[418]

Similar to the way industry had used PR firms to spin its message that opioids could be widely used without risk, the HDA also utilized industry PR consulting firms to spin its false message that Defendants were taking their compliance obligations seriously.[419]

Anti-Diversion Industry Working Group ("ADIWG")

ADIWG was an industry front group that included AmerisourceBergen, Cardinal, McKesson, Mallinckrodt and other entities. It was formed as a public relations vehicle to promote an impression of industry efforts in preventing diversion, while simultaneously deflecting distributors' and manufacturers' responsibility for the Opioid Epidemic. ADIWG touted in a letter to DEA: "Aside from our own anti-diversion activities in helping to protect the drug supply chain, many of our respective organizations have established educational programs for healthcare professionals and outreach programs to communities to help educate and inform all parties on the dangers associated with prescription drug abuse."[420] In 2014, ADIWG and the National Association of Boards of Pharmacy produced a video entitled "Red Flags," ostensibly to educate pharmacists about "the presentation of a controlled substance prescription that should raise

[415] HDA_MDL_000084666; HSI-MDL-00620224 at 225; HDA_MDL_000143030; CAH_MDL2804_01521412; CAH_MDL2804_02489188; HDA_MDL_000156499; HDA_MDL_000142905; HDA_MDL_000118385; HDA_MDL_000093755; HDA_MDL_000117145; HDA_MDL_000117158.

[416] CAH_MDL2804-02489188; HSI-MDL-00620224 at 225.

[417] Kelly Dep., at 241:13-242:8 and 248-49; HDA_MDL_000080421; CAH_MDL2804_02489188 at 189; HDA_MDL_000155886; HDA_MDL_000155930; HDA_MDL_000081415.

[418] HDA_MDL_000155930 at 936; HDA_MDL_000081415.

[419] HDA_MDL_000087762 (and attachments); MCKMDL00586952; Kelly Dep. 345:18-347:23; CAH_MDL2804_01505341; HDA_MDL_000087762; 000087734-54; HDA_MDL_000087806 at 000087809; PPLPC031000302888 (6/5/2006 email in which Dezenhall's Sheila Hershow sent Purdue a transcript of Dateline NBC story ordered by HDMA); HDA_MDL_000159557 (5/17/2007 Executive Committee Meeting Minutes); HDA_MDL_000202605.

[420] CAH_MDL2804_03250272.

reasonable suspicion about the validity of that prescription." This video, however, served to put the onus on pharmacists, rather than distributors and manufacturers, to prevent diversion.[421]

Additionally, the ADIWG lobbied DEA to advance rules that put the onus on DEA to prevent diversion and minimized the responsibility of manufacturers and distributors rather than accept their role in the system and work to prevent diversion and protect public health and safety.[422]

Had the Defendants acted as prudent distributors of narcotics, they would have complied with their obligations as DEA registrants and maintained adequate systems to prevent diversion. Instead, the Defendants repeatedly issued false statements to policymakers and the public about the adequacy of their anti-diversion programs. In so doing, they prevented state and federal policymakers from more forcefully regulating them. The Defendants worked to preserve the profitable status quo despite the clear and devasting impact they were having on families and communities across the country and especially in West Virginia.

g. Defendants funded and fueled a massive campaign to dismantle rules, regulations and government control designed to check supply and protect the public

Within the first few years of the release of OxyContin, serious public health problems related to its use, especially in Appalachia and New England, began to emerge.[423] To prevent policymakers, the medical community and the public from responding appropriately to this newly emerging public health crisis, Purdue Pharma and its industry partners would adopt a public relations strategy that falsely framed the problem. "We have to hammer on the abusers in every way possible," Purdue's Richard Sackler wrote in a confidential email in 2001. "They are the culprits and the problem. They are reckless criminals."

The strategy that Sackler was describing, one the Defendants would adopt, was to falsely frame all of the harms caused by the soaring increase in opioid supply as limited to a small subset of "abusers" while claiming that the increasing supply was helping millions of people with chronic pain. Purdue hired Dezenhall Resources, a crisis management public relations firm (also hired by HDA), to attack fair media coverage of the crisis and to push this false narrative.[424] When Kathy

[421] MNK-T1_0005543594.

[422] *See e.g.* ABDCMDL00169253 (2018 draft petition to DEA for rulemaking on SOM, noting that DEA is "uniquely situated" to "lead the effort to eradicate diversion," while manufacturers and distributors have "limited visibility" to only their customers). ADIWG also criticized DEA guidance as wrongfully shifting responsibility to the industry.

[423] Meir B. 2003. Pain Killer: A "Wonder" Drug's Trail of Addiction and Death. Rodale Inc.

[424] Armstrong D. Inside Purdue Pharma's Media Playbook: How It Planted the Opioid "Anti-Story": OxyContin's makers delayed the reckoning for their role in the opioid crisis by funding think tanks, placing friendly experts on leading outlets, and deterring or challenging negative coverage. Propublica Nov. 19, 2019.

Foley, a prominent opioid industry key opinion leader, suggested the formation of the Pain Care Forum in an email to Richard Sackler, it was evident that she had a media strategy in mind:

> "…we should call a meeting, bring together representatives from all of the companies, ideally high level representatives, like presidents or major leaders and strategize about the way to play the media issues."[425]

The Pain Care Forum formed shortly after this email from Dr. Foley. In opposing state and federal interventions that might reduce the massive oversupply of opioids, the Pain Care Forum consistently claimed it was defending the interests of patients with chronic pain.[426] Efforts that might result in a decreased supply were described by Pain Care Forum members as harmful to pain patients. In blocking efforts to limit opioids, such as an effective REMS program, hydrocodone up-scheduling, CDC guidelines or when pushing through legislation to weaken the DEA's enforcement authority over the Defendants, the need to "ensure access" for patients with chronic pain was always claimed. In reality, opioids are neither safe nor effective for chronic pain and people suffering with pain have been disproportionately harmed by aggressive opioid use.

Unfortunately, this tactic was successful. Interventions and polices that might have helped bring the opioid crisis under control were avoided or delayed because of fear of impeding access to opioids for patients suffering from pain. Meanwhile, millions of Americans were becoming addicted to opioids, thousands were losing their lives to opioid-related overdoses and the devastating epidemic of opioid addiction continued unabated.

Between 2006 and 2015, the Pain Care Forum's members spent nearly $900 million to influence government on issues critical to their industry, including measures to prevent state and federal policymakers from taking actions that might limit the supply of opioids.[427]

i. The Marino Bill- Defendants Dismantle the DEA's power

At the height of the deadliest drug epidemic in U.S. history, Defendants worked behind the scenes through HDMA and with their team members in the opioid industry through the Pain Care Forum to weaken and dismantle the DEA's authority to regulate the opioid industry. Defendant Cardinal Health went so far as to secretly push for ending the DEA's authority to regulate the opioid supply chain in a Wall Street Journal op-ed penned by Scott Gottlieb.[428]

[425] PPLPC037000008901.

[426] Perrone, M. et al. (2016): Pro-painkiller echo chamber shaped policy amid drug epidemic. https://publicintegrity.org/state-politics/pro-painkiller-echo-chamber-shaped-policy-amiddrug-epidemic/

[427] http://data.ap.org/projects/2016/cpi_ap_opioids/indexcpiap.html.

[428] Gottlieb S. *The DEA's War on Pharmacies-and Pain Patients*. Wall Street Journal. March 22, 2012, *available at* https://www.wsj.com/articles/SB10001424052702304636404577297332734154326.

Undisclosed in the op-ed was Cardinal Health's involvement in developing the piece and its financial ties to Scott Gottlieb.[429]

Through what was referred to as "the Marino Bill," named after its sponsor Rep. Tom Marino, the opioid industry was able to weaken sections of the CSA which allowed the DEA to immediately suspend registrations prior to an administrative revocation proceeding, in cases "where [the DEA] finds that there is an imminent danger to the public health or safety." That powerful tool was regularly and cautiously used by the DEA to shutdown pill mills and to compel the Defendants' compliance with their CSA duties. The proposed revision pushed by Defendants and their trade organization successfully stripped the DEA of this most potent weapon. Called "the Ensuring Patient Access and Effective Drug Enforcement Act," the Bill raised the DEA's standard for suspending drug shipments by requiring that the agency establish "a significant and present risk of death or serious bodily harm that is more likely than not to occur."

The industry fueled Marino Bill came in response to years in which the DEA had attempted to crack down on an out of control supply that resulted from Defendants disregard for their obligations under the CSA. For years, Defendants and other members of the opioid supply chain were fined for repeatedly ignoring warnings from the DEA to cease filling suspicious orders. Instead of heeding these warnings and actions as prudent distributors of narcotics, Defendants and the opioid industry set out to dismantle the DEA's power to enforce the CSA. Shortly after the DEA suspended Cardinal's Lakeland facility, the HDA began considering a legislative strategy for "alter[ing] the present direction DEA is taking with respect to suspicious order monitoring." The Defendants shared goal, articulated by the HDA, was to "develop a comprehensive DEA strategy" to avoid enforcement actions being taken against their members.

Notably, when the HDA met with outside counsel to obtain recommendations on "potential actions the [HDA] and the industry may consider in an effort to alter the present direct[ion] DEA is taking with respect to suspicious order monitoring," the lawyers "felt that we may be better off averting DEA actions by taking even stronger compliance measures." The distributors rejected that advice.

Instead, the distributors pursued a strategy to weaken the DEA's enforcement capabilities in part through the Marino Bill. They found an ally in former DEA Associate Chief Counsel, Diversion and Regulatory Litigation Section, Linden Barber. Barber had been part of the DEA Distributor Initiative, a strategy to go after the Defendants and other distributors for their role in flooding communities with pills and allowing rampant diversion. Mr. Barber left DEA in 2011 and went into private practice, where he immediately began counselling the very companies he had targeted as a regulator. One of his first tasks was authoring and advocating for the Marino Bill.

By December 2013, the HDA identified the "issu[ance of a] statement of support for Marino/Blackburn legislation," as a strategy for dealing with the DEA's approach to diversion. That draft legislation, authored by Barber, included a new statutory definition of "imminent danger to the public health or safety" and "would allow DEA registrants the opportunity to

[429] CAH_MDL2804_02505518-520; MNK-T1_0005783676-678.

submit a corrective action plan to address specific concerns that could otherwise lead to the suspension or revocation of a registration." That is, the draft legislation stripped the DEA of the ability to issue an immediate suspension order against a drug manufacturer or distributor whose unlawful conduct poses an imminent danger to the community.

The distributors, through the HDA, turned to the Pain Care Forum (PCF), described in Section _, to coordinate support for passing the Marino Bill. As Purdue's in-house lobbyist explained, the Marino bill "was created by the HDMA and NACDS" to "not allow DEA to charge in and close them down" and "cut[] supply chain access."[430] Defendants, through the HDA, asked the PCF to support the bill.[431] Non-industry Pain Care Forum members signed letters that the HDA drafted in support of the Bill. Thus, Defendants used their memberships in multiple organizations to make it appear that the Marino Bill had widespread support from neutral third parties. One such group was the Alliance to Prevent the Abuse of Medicines, whose members included CVS, Cardinal Health, Teva, and the HDA (as an advisory member). When the Alliance was asked to sign on to a 2014 letter of support it was "signed by the Alliance, not the individual members." The final letter that was sent to Senators Hatch and Whitehouse was signed by the members of the Pain Care Forum as well as the Alliance, the NACDS, American Academy of Pain Management, and U.S. Pain Foundation, all of whom were comprised of opioid industry members or funded by the opioid industry. Linden Barber went to capitol hill to advocate for the bill's passage.

The DEA opposed the law because it limited its ability to suspend registrations as a critical part of its enforcement authority. The HDA supported it for this exact reason. HDA's Executive Committee directed the HDA to: "exhaust all efforts to secure passage of [the Marino Bill]." The enacted version of the Marino Bill became law with a new statutory definition of "imminent danger to the public health or safety." The law made it next to impossible for the DEA to impose an immediate suspension on drug distributors, manufacturers and pill mills. As the DEA's Chief Administrative Law Judge explained, "If it had been the intent of Congress to completely eliminate the DEA's ability to ever impose an immediate suspension on distributors or manufacturers, it would be difficult to conceive of a more effective vehicle for achieving that goal."[432] Forty-Four State Attorneys Generals were more blunt, stating that the law "effectively strips the [DEA] of a mission-critical tool" and called for its repeal.[433]

The bill passed on April 19, 2016. Cardinal Health congratulated Purdue for its help in passing the Marino bill, calling it "team effort by all of us."[434] After achieving this coup for industry, Linden Barber then went on to become the Chief Regulatory Counsel and SVP for Cardinal

[430] PPLP004267403.

[431] PPLP004267618.

[432] Mulrooney, II, J., Legel, K. *Current Navigation Points in Drug Diversion Law: Hidden Rocks in Shallow, Murky, Drug-Infested Waters*, 101 MARQ. L. REV. 333, 347 (2017).

[433] The letter is attached to a PCF email, PPLPC017000798471.

[434] PPLPC0190012650.

Health, and is now acting Executive Vice President of Quality and Regulatory Affairs for the Cardinal Health. Joseph T. Rannazzisi, who ran the DEA's division responsible for regulating the drug industry was quoted as saying, "I mean, to get Congress to pass a bill to protect their interests in the height of an opioid epidemic just shows me how much influence they have."

ii. REMS

In 2007, Congress gave the FDA a new authority over pharmaceutical companies that manufacture dangerous medications.[435] The law allowed FDA to require these companies to operate programs called Risk Evaluation and Mitigation Strategies (REMS) to reduce the risks associated with these drugs.

In 2008, while contemplating a REMS program requirement for manufacturers of extended-release and long-acting (ER/LA) opioids,[436] FDA asked the companies making these products to form an Industry Working Group to coordinate their position.[437] These Industry Working Group meetings would be on the record and attended by antitrust counsel.[438] FDA's proposed IWG did not include key players such as HDA, Defendants and various front groups.[439]

In a March 2009 meeting with manufacturers of ER/LA opioids, FDA outlined its plan for the REMS programs.[440] The FDA's proposal included a requirement for prescribers to obtain a certification to prescribe ER/LA opioids."[441] The FDA proposal also called for certifications for pharmacists that would "reflect that persons dispensing the drug (e.g., pharmacists or hospital personnel) are familiar with educational materials, risks of the drug and conditions for safe use." Lastly, the proposal included a plan for a "database of all enrolled entities including prescribers, pharmacies, practitioners and healthcare settings."

As an advocate for more cautious opioid use, I recall applauding the FDA's proposed plan because I believed it would reduce the supply of these ER/LA opioids. I expected that many clinicians would opt-out from getting certified, thus reducing the pool of clinicians able to prescribe these products and I believed it would be helpful to ensure that those who did prescribe

[435] PPLPC051000064077 (Food and Drug Administration Amendments Act of 2007).

[436] Burt Rosen [Purdue] Deposition (Jan. 16, 2019), at 191:1-9.

[437] EPI000066634 (IWG Submission to FDA Docket detailing FDA's request to form IWG); EPI001059511.

[438] PPLP004299456 (Meeting minutes of first IWG meeting); Rosen Deposition at 237:12-16 (IWG meetings were attended by antitrust counsel).

[439] Rosen Deposition at Ex. 27 at 6 (IWG presentation listing IWG members).

[440] PPLP004065860-878 (Slide presentation by FDA on proposed Risk Evaluation and Mitigation Strategies).

[441] *Id.*

or dispense were trained in opioid risks. I also believed that the proposed database would help prevent diversion.

The opioid industry, through the Pain Care Forum, immediately set out to "coordinate strategy and address the FDAs REMS proposals."[442] The Pain Care Forum and its members, formed its own working group (the "internal IWG)" to address the threat to industry that a robust REMS would pose.[443]This internal IWG had a very different goal than protecting public health, revealed in internal documents stating that the FDA's goal for REMS was to "Reduce serious adverse outcomes resulting from inappropriate prescribing, misuse, and abuse of long acting and extended-release opioids while maintaining patient access to these medications" and that this goal "*differs* from the goal proposed by the Industry Working Group (IWG)."[444]

The Pain Care Forum's strategy included a plan to push media stories to "highlight the blurring of responsibilities between FDA and other agencies, and the impact this may have on patient care and access to appropriate medications" and "that the abuse and diversion problem should not, and could not, be solved on the backs of people with pain."[445]As in other efforts by the Pain Care Forum, there was agreement that industry players should operate behind the scene with a public plan that "should be driven by the not-for-profit community, potentially with multiple industry sponsors."[446]

The HDA's Senior Director for Regulator Affairs, Anita Ducca, participated on the Pain Care Forum's REMS task force. According to her HDA personnel evaluation at the time, the goals of her position included "**Seek to moderate federal government and related requirements for distributors, including controlled substances initiatives**" and "Strive to ensure FDA "buy-in" of the distributors' position on "restricted distribution" REMS."[447]

Defendants used the PCF to present what, from the FDA's perspective, must have appeared as a diverse group of stakeholders, including professional organizations, "grass roots" patients groups and health care providers all submitting separate but similar comments to a federal docket on the proposed REMS from prepared "recommendations".[448] When one PCF member raised concern that the FDA "may feel it was rather duplicitous of the [industry members] to meet with

[442] Rosen Deposition at 191:1-9.

[443] EPI001059511 (2008 Will Rowe email RE: PCF REMS Task Force with recipients from organizations including APHA, PPSG, Allergan, Endo, Purdue, J&J, NHPCO, Cephalon, HDMA, and APF); Rosen Deposition at Ex. 23, Ex. 24, and Ex. 25 (PCF emails re REMS Task Force, including email from HDMA commenting on proposed letter to FDA).

[444] *See also* Rosen Deposition at Ex. 27 at 10.

[445] PPLP004298301-303 (Summary of Pain Care Forum Media Committee).

[446] *Id.*

[447] HDA_MDL_000117003-004 ("Updated Goals" for Anita Ducca)(emphasis added).

[448] *See* Rosen Deposition at Ex. 27 at 12, 28.

[the FDA commissioner] and not mention that these were in the works," he was told, "It's the way things work" and there was a "need to keep silent on the congressional and media strategies."[449]

The PCF Task Force reviewed a draft letter to the FDA that included discussion of mandatory physician and pharmacist training and certification requirements as a prerequisite to prescribing and dispensing ER/LA opioids.[450]The PCF, working with the HDA, deleted that part, stating "we shouldn't mention a 'certification' requirement for physicians (or anyone else for that matter.)"[451] The final letter to the FDA did not mention the HDA's or the PCF's role in drafting the letter.[452]

The effort by HDA and the PCF to weaken the opioid REMS was highly effective. The FDA responded to their efforts by removing from its REMS proposal all elements that would have reduced the supply of opioids. FDA's revised final plan was so weak that when it was presented to an external expert Advisory Committee, the plan was voted down 25-10.[453] When asked at the meeting to explain their vote against the FDA proposal, multiple committee members explained that the REMS "lacked teeth."[454]

iii. CDC Guidelines

In late 2016, as the CDC was finalizing a guideline calling for more cautious prescribing, the opioid industry mounted an effort to block its release.[455] As it became clear that their efforts would fail, the opioid industry adopted a new strategy. It successfully lobbied for legislation that

[449] PPLP003985888; PPLP004051807 at 808.

[450] Rosen Deposition, at 198:16-205:21, 206:21-210:15; Ex. 23 (draft letter to FDA); Ex. 24 at 5 (draft letter stating, "we *encourage* FDA to implement targeted prescriber and pharmacist education with appropriate confirmation requirements as a prerequisite to prescribing and dispensing these products.") (emphasis added); PPLP004052907 (Will Rowe email acknowledging "We hope to develop a letter that is amenable to all the principal stakeholders. . .").

[451] Rosen Deposition at 210:16-215:6; Ex. 25 (HDMA comment on draft stating "For now we shouldn't mention a certification requirement for physicians or anyone else, for that matter."); EPI001038487 (email from Will Rowe to the PCF REMS Task Force that "reflects the concerns" expressed in meetings and is a "keep it simple" letter).

[452] Rosen Deposition at Ex. 26 at 6-7 (final version of letter sent to FDA); Rosen Deposition at 220:13-14 (confirming "That language is not in there"); ENDO-OPIOID_MDL-02212590.

[453] Transcript of the Joint Meeting of the Anesthetic and Life Support Drugs Advisory Committee (ALSDAC) & Drug Safety and Risk Management Advisory Committee (DSaRM), July 23, 2010 12, 8:00 a.m. to 3:30 p.m.

[454] *Id.*

[455] Perrone, M. et al. (2016): Pro-painkiller echo chamber shaped policy amid drug epidemic. https://publicintegrity.org/state-politics/pro-painkiller-echo-chamber-shaped-policy-amiddrug-epidemic/

create a government task force stacked with front group members, to issue a competing guideline.[456] The HDMA spent $1.2 million to support this legislation.[457]

The effort was successful. Section 101 of the Comprehensive Addiction and Recovery Act of 2016 called for a task force on pain management which in 2019 issued opioid prescribing recommendations that contradicted guidance from the CDC.[458]

iv. Scheduling hydrocodone combination products

When the Controlled Substances Act (CSA) was passed, one of its primary purposes was to place drugs with similar abuse liability into distinct categories called schedules. This sensible approach to categorizing narcotics made it possible to link regulations to a drug's schedule, allowing for easier access to drugs with less risk, while maintaining greater restrictions on riskier drugs. In addition, the scheduling of drugs created a mechanism for informing the medical community and the public about how addictive a particular drug might be.

There is an important rule that must be followed for the scheduling of drugs to have the effect the CSA intended. Drugs with similar abuse liability and addiction potential must be placed into the same schedule. If drugs are incorrectly scheduled, the system falls apart. For example, if a highly addictive drug is incorrectly placed in a category intended for drugs with lower abuse liability, then prescribers, patients and even teenagers curious about experimenting with the drug, might underestimate risks. In addition, the ability to reduce diversion and inappropriate availability of the drug in classrooms, college dormitories and on the black market will be hindered. This was exactly the situation with hydrocodone combinations products before theses drug was correctly scheduled in 2014.

In 1970, when the CSA was drafted, hydrocodone combinations products were incorrectly scheduled. At the time, hydrocodone's potency was not well understood. Evidence of this can be found by comparing the amount of hydrocodone permissible in a Schedule III combination product to the amount of morphine that is permitted in a Schedule III combination product. Whereas the CSA's Schedule III category permits up to 15mg of hydrocodone in a pill containing 325 mg of acetaminophen (APAP), it only allows up to 0.16mg of morphine in combination with 325mg of APAP. This suggests that when the CSA was written, morphine was believed to have a far higher potency than hydrocodone.

We know today that the potency of oral hydrocodone is at least equal to the potency of oral morphine. This error in the CSA explained why Vicodin (hydrocodone-APAP) was Schedule III and Percocet (oxycodone-APAP) was Schedule II, even though Vicodin and Percocet have a similar abuse liability.

[456] Lurie J. Big Pharma Has a Big Role on the Federal Committee Tasked With Curbing Opioid Abuse. May 19, 2019.

[457] *Id.*

[458] *Id.*

In 2004, with mounting evidence of diversion, abuse and addiction, a DEA analysis concluded that needed to be up-scheduled for reasons that included the following[459]:

- Human and animal studies indicate that hydrocodone is equipotent to morphine, has an abuse liability similar to morphine and produces effects that are indistinguishable from morphine.
- Hydrocodone combinations products are associated with significant diversion and are "the most frequently encountered opiate pharmaceutical in forensic laboratory submissions of drug evidence."
- hydrocodone combinations products are among "the most widely abused" pharmaceuticals in the United States.
- No data can be found to support keeping HC's in the less restrictive Schedule III category.

Despite the clear public health need to close the scheduling loophole for hydrocodone combinations products, the opioid industry, including HDA and NACDS mounted a campaign to block up-scheduling of hydrocodone combinations products.[460]

h. In blatant disregard for public health and safety, including that in the Huntington-Cabell Community, the Defendants refused to take responsibility for the epidemic, even today, and even tried to shift blame to others, including the people they helped addict to opioids.

In 2018, as the Opioid Epidemic raged in West Virginia impacting communities and families across the state, including the Cabell-Huntington Community, each of the Defendants stood before the United States Congress and denied any responsibility. The witnesses testified:[461]

George Barrett: CEO Cardinal Health:

Q. First, do you believe that the actions that you or your company took contributed to the Opioid Epidemic?

[459] FDA Briefing Document Drug Safety and Risk Management Advisory Committee (DSaRM) Meeting – January 24-25, 2012. Available at: https://wayback.archive-it.org/7993/20170405214207/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/DrugSafetyandRiskManagementAdvisoryCommittee/UCM334276.pdf

[460] Pear R. Lobbying Effort Is Said to Sink New Controls on Painkillers. New York Times. June 18, 2012.; ENDO-OPIOID_MDL-02301476; HDA_MDL_000020031 at 035 *Minutes of the HDMA Executive Committee Meeting, June 10, 2012).

[461] Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, 115th Cong., 49-50 (2018) available at https://docs.house.gov/meetings/IF/IF02/20180508/108260/HHRG-115-IF02-Transcript-20180508.pdf.

> Mr. Barrett. **"No. No, sir, I do not believe that we contributed to the opioid crisis."**
>
> Jon Hammergren: CEO McKesson:
>
> Q. Mr. Hammergren.
>
> Mr. Hammergren. **No.**
>
> Steve Collis: CEO Amerisource Bergen
>
> Q. Okay. Mr. Collis.
>
> Mr. Collis. **No. I believe we -- it's a no for AmerisourceBergen.**

Asked at the hearing whether their companies previously failed to maintain effective controls to prevent opioid diversion, distributor witnesses acknowledged that in hindsight they could have done more. Mr. Barrett of Cardinal Health apologized to West Virginians for Cardinal's actions, testifying that if the company were presented with the same red flags today, it would have more carefully vetted some of the pharmacies in question:

> To the people of West Virginia, I want to express my personal regret for judgments that we'd make differently today with regard to two pharmacies that have been a particular focus of this subcommittee. With the benefit of hindsight, I wish we had moved faster and asked a different set of questions. I'm deeply sorry that we did not.

Mr. Hammergren of McKesson expressed similar sentiments, noting that "there clearly were certain pharmacies in West Virginia that were bad actors." While Mr. Hammergren noted that McKesson terminated business relations with some West Virginia pharmacies, he said "[i]n hindsight, I would have liked to have seen us move much more quickly to identify the issues with these pharmacies." Mr. Collis of AmerisourceBergen denied that his company played a role in the Opioid Epidemic, and said it always fulfilled its legal obligations to combat diversion, including with respect to its shipments to West Virginia. Nevertheless, Mr. Collis conceded the massive volume of opioids that flooded small towns in West Virginia could have been a symptom of an industry-wide problem.

HDA/HDMA and the Defendants developed a comprehensive media strategy to counter negative coverage about the Defendants' role in contributing to the opioid crisis. In 2013, HDMA (along with the PR firm APCO) produced the "Crisis Playbook" for itself and the Distributors, which included "response procedures, best practices and the names and contact information of a cross-functional task force that has the authority to act quickly and decisively in response to critical reputational and crisis issues."[462]

[462] ABDCMDL00288483 (email summarizing Playbook); ABDCMDL00288484 (revised edition of Crisis Playbook). This "Crisis Playbook" also served as a tool for its members, including the Big 3, to respond to "scrutiny from the media as well as the legislators and regulators . . . on a range of issues, including prescription drug abuse and diversion" *See* Gray Dep. at 89:21-90:11. The playbook contained suggested answers to "tough questions that a distributor might be asked". *Id*. at 95:11-12. For example, in response

In 2015, a West Virginia state lawsuit asserted that distributors flooded the state with over 200 million painkillers during a 4-5 year period. In response, HDMA mounted a comprehensive strategy and specific timeline to "Turn the Tide" of "imbalanced" media coverage in West Virginia through outreach to the public, media and political leaders; convening a summit; and generally blanketing the state with pro-distributor messaging.[463]

In 2017, HDA and the Defendants mounted a campaign against the Washington Post and 60 Minutes coverage of the Opioid Epidemic. The campaign included social media advertising and messaging on Facebook, Twitter and LinkedIn; materials on HDA's website, including a "fact check" blog and media statement; and a push to influence legislators.[464]

When the Distributors needed to be aggressive in lobbying or public affairs, they instructed HDA/HDMA to handle it for them to avoid negative public perception. HDA/HDMA lobbied federal and state politicians but instructed HDA rather than the individual Distributors to participate, so as to avoid the perception that the Distributors were directly lobbying themselves.[465]. At times, there was dissention among the HDA and its member organizations about how aggressively the organization should pursue the Defendants' goals.[466]

Apparently, the Defendants believe their expensive PR campaigns have worked, at least in part, seeing "progress" in the press coverage in 2017.[467]

to a question about how "these large publicly traded companies are making millions of dollars from diversion of prescription drugs", the playbook recommended answering that "[p]atient safety is put before profits". *Id*. at 95:13-96:3.

[463] ABDCMDL00269293, ABDCMDL00269301 (6/19/2015 memo and presentation to HDMA members).

[464] ABDCMDL03830243 (email chain noting that "HDA would take the lead," and discussing HDA's social media and internet strategy to "take this head on"); CAH_MDL2804_00112004 (10/13/17 note to Cardinal employees from George Barrett dismissing unfair and "one-sided" allegations in 60 Minutes/WaPo stories, noting that Cardinal "chose not to appear on-camera because of the editorial choices we saw them making," and referring employees to HDA website).

[465] PPLPC020001151103 (11/9/17 email chain). In fact, John Gray testified in front of Congress on behalf of the HDMA and its defendant members "[p]robably 10 or 12 times at least". *See* Gray Dep. at 80:1-10.

[466] *See* ABDCMDL00375084 (1/27/18 email in which AmerisourceBergen expressed frustration that HDA and McKesson are not being aggressive enough on issues related to the Washington Post story, and Amerisource's Gabe Weissman stated: "I believe the strength of a trade association on topics like this is that they are able to say the things we can't/won't and I typically try not to put us in a position to 'sign off' on the more aggressive materials.")

[467]ABDCMDL03829334 (1/27/2017 internal Amerisource email discussing ProPublica story about distributors "Turning Blind Eye in Opioid Epidemic," and noting that while tone was negative, information from HDA was included in the story that suggested DEA was partly at fault).

Internally, however, the Defendants recognized that they were "contributing to the problem."[468] In 2013, McKesson conducted an internal presentation, well before many of these public denials detailing exactly how McKesson was contributing to the epidemic including, shipping "only the specific drug of choice, in an exorbitant amount, in the primary strength, to the known epicenter of diversion, to a customer they had never dealt with in the past- AND- then doing it repeatedly"[469] and "ship[ing] multiple orders, in the primary strength, to the known epicenter of diversion, to a customer suspected of being involved in diversion."[470] McKesson's presentation details the litany of distributor excuses for not following their compliance obligations, many of which these companies continue to raise, and quickly dispenses with those obligations by illustrating a different list of how many ways since 2007 these companies were warned, educated, told and admonished, putting them on clear notice that they were failing in those obligations and must do better.[471] By 2014, McKesson noted internally that "every component of the distribution chain has been breached."[472]

5. The conduct of the Defendants, working individually and together, was a substantial factor in causing the Opioid Epidemic. Working closely and in an intertwined and interlinked system with their business partners in the supply chain (namely the opioid manufacturers and chain pharmacies) without reasonable care, their abnormally dangerous behavior and blatant violations of the laws and regulations combined to cause the Opioid Epidemic we see today.

Before the multifaceted campaign to increase the supply of prescription opioids was launched by the opioid industry, including the Defendants, the incidence of opioid addiction in the United States and West Virginia was low. Had the Defendants acted as prudent distributors of narcotics, I believe the incidence would have remained low.

1) Prudent distributors of narcotics drugs would not have participated in a campaign to increase the supply of opioids, as the Defendants did.

2) Prudent distributors of narcotics would not have repeatedly shipped narcotics to corrupt pharmacies, as the Defendants did. Instead, they would have maintained robust systems to detect diversion.

3) Prudent distributors would not have ignored clear evidence that the opioids they were shipping were fueling a public health catastrophe and destroying communities and families across the country, as the Defendants did.

[468] MCK-AGMS-006-0000904-905.

[469] MCK-AGMS-006-0000904.

[470] MCK-AGMS-006-0000905.

[471] MCK-AGMS-006-0000906-907.

[472] MCKMDL00407451.

4) Prudent distributors of narcotics would not have participated in a campaign to deceive policymakers and the public about the adequacy of their monitoring systems or mis framed the opioid crisis to preserve the status quo that was benefitting them financially.

It is my opinion that these serious failures by the defendants were a substantial cause of the Opioid Epidemic in the United States, West Virginia and in the Huntington-Cabell Community.

6. The harm to public health, safety and welfare in Plaintiffs' Communities caused by Defendants' conduct was not only unreasonable, it was foreseeable and preventable.

Opioids are Schedule II narcotics with a high potential for abuse. One need only look at the drug's long history with addiction to understand that addiction and all of the negative societal consequences would ensue when people were widely exposed to these highly addictive narcotics (see Section VI(1)-(3)).[473] The opioid drugs Defendants were supplying in large amounts to the United States, West Virginia and the Cabell-Huntington Community were no different and no less addictive. Indeed, (as discussed in Section VI (1), in the high doses and for long durations, they were more so (see Section VI(3)).

As thoroughly detailed above, exposure caused the epidemic of addiction we see in the Cabell-Huntington Community today. In fact, exposure to addictive drugs like opioids is a key element of causing the predictable harm of addiction and the consequences that flow from it (*see* Section VI(1)-(3). McKesson testified that "[t]he volume of opioids in the market and diversion is related to opioid deaths, certainly."[474]

As soon as a population was hooked on prescription opioids, it was also foreseeable that those individuals would transition to illicit opioids and other illegal drugs (see Section VI(3). Indeed, as McKesson's corporate representative testified, "abuse of prescription opium pills is a gateway to the initiation of heroin" and that it "is a driving factor in the heroin epidemic".[475]

With more supply of a dangerous controlled substance, there will be more diversion. As conceded by McKesson "major diversion schemes cannot exist without supply."[476] And Amerisource Bergen admitted that harm was foreseeable if registrants in the closed system did not prevent diversion and comply with the CSA.[477]

[473] *See also,* Expert Report of David Courtright.

[474] Nate Hartle [McKesson] Deposition (July 31, 2018) at 294:15-17.

[475] *Id*. at 320:14-321:10.

[476] MCK-AGMS-006-0000925; *see also,* Hartle Deposition at 298:18-299:17.

[477] See Chris Zimmerman [AmerisourceBergen] Deposition (August 3, 2018) at 104:14-17.

Defendants' practices could prevent this foreseeable diversion. Indeed, it was their legal obligation to do so if they wished to sell prescription opioids.

7. Even with the Proper Interventions, the damage to public health, safety and welfare in the Huntington-Cabell Community has been and will continue to be a long-lasting and deeply devastating public health disaster.

As discussed in Section VI(1), opioid addiction is a chronic disease. Once an individual develops opioid addiction it will often impact them (and their families) for the rest of their lives. Because of the actions of the Defendants, the number of people in the United States, West Virginia and in the Huntington-Cabell Community suffering from opioid addiction increased exponentially (Kolodny et al. 2015). Even with a robust abatement program to prevent new cases of opioid addiction and to ensure access to treatment for the Defendants' victims, I believe the Huntington-Cabell Community will experience health and social problems for several decades, including problems stemming from the large cohort of opioid-addicted individuals as well as the inter-generational effects of addiction.

8. There are evidence-based solutions that can be implemented, albeit over time and with the right resources, that can turn the tide of the epidemic in the Huntington-Cabell Community and should be implemented.

Despite the high prevalence of opioid addiction that will impact the Cabell-Huntington Community for decades, there are interventions that, over time and with the right resources can help turn the tide of the Opioid Epidemic in the community. These interventions should focus on preventing new cases of opioid addiction (primary prevention), identifying early cases of opioid addiction (secondary prevention), and ensuring access to effective addiction treatment (tertiary prevention). They should focus on harm reduction, preventing opioid overdose and death and public health interventions to prevent or slow the spread of communicable diseases like HIV and Hepatitis A.

Primary Prevention

The aim of primary prevention is to reduce the incidence of a disease or condition. Opioid addiction is typically chronic, life-long, difficult to treat, and associated with high rates of morbidity and mortality. Thus, bringing the opioid addiction epidemic under control requires effort to prevent new cases from developing.

Preventing addiction caused by medical exposure to opioids. The incidence of iatrogenic opioid addiction in patients treated with long-term opioids is unknown because adequately designed prospective studies have not been conducted. However, opioid use disorders appear to be highly prevalent in chronic pain patients treated with opioids. A survey performed by Boscarino et al. of 705 chronic pain patients treated in specialty and primary care outpatient centers found that 26% met the Diagnostic and Statistical Manual of Mental Disorders (DSM) IV criteria for opioid dependence, and 35% met DSM V criteria for an opioid use disorder.[478] A systematic review of

[478] Boscarino JA, et al. (2010). Risk factors for drug dependence among out-patients on opioid therapy in a large US health-care system. *Addiction*, 105(10), 1776–82. doi: 10.1111/j.1360-0443.2010.03052.x;

studies utilizing opioids for low back pain found that aberrant drug abuse–related behaviors suggestive of addiction occurred in up to 24% of patients on long-term opioids.[479] Many patients on long-term opioids worry about dependence and addiction and express a desire to taper or cease opioid therapy.[480]

To reduce the incidence of opioid addiction caused by medical treatment, health care professionals must prescribe opioids more cautiously for both acute and chronic pain. Unfortunately, the campaign to encourage opioid prescribing has left many health care providers with a poor appreciation of opioid risks, especially the risk of addiction, and an overestimation of opioid benefits. Despite these risks and the lack of evidence supporting long-term efficacy, opioid prescribing for chronic non-cancer pain increased until 2012 while use of nonopioid analgesics decreased.[481] This pattern highlights the need for prescriber education that explicitly corrects misperceptions about prescription opioid safety and efficacy. If clinicians treating pain more often substituted nonopioid analgesics and nonpharmaceutical approaches for opioids, evidence suggests the incidence of opioid addiction would decline and outcomes for patients with chronic non-cancer pain would improve.

Many prescribers remain unaware that evidence of long-term effectiveness for opioids is lacking and that risks, in addition to addiction, include respiratory depression leading to unintentional overdose death; serious fractures from falls;[482] hypogonadism and other endocrine effects that can cause a spectrum of adverse effects;[483] increased pain sensitivity;[484] chronic constipation and

Boscarino JA, et al. (2011). Prevalence of prescription opioid-use disorder among chronic pain patients: comparison of the DSM-5 versus DSM-4 diagnostic criteria. *J. Addict. Dis*, 30(3), 185–94. DOI: 10.1080/10550887.2011.581961.

[479] Martell BA, et al. (2007). Systematic review: opioid treatment for chronic back pain: prevalence, efficacy, and association with addiction. *Ann. Intern. Med*, 146(2), 116–27. doi: 10.7326/0003-4819-146-2-200701160-0000

[480] Sullivan MD, et al. (2010). Problems and concerns of patients receiving chronic opioid therapy for chronic non-cancer pain. *Pain* 149:345–53.

[481] Daubresse M, et al. (2013). Ambulatory diagnosis and treatment of nonmalignant pain in the United States, 2000–2010. *Med. Care* 51(10), 870–78. doi: 10.1097/MLR.0b013e3182a95d86

[482] Saunders KW, et al. (2010). Relationship of opioid use and dosage levels to fractures in older chronic pain patients. *J. Gen. Intern. Med*. 25(4), 310–15. doi: 10.1007/s11606-009-1218-z; Takkouche B, et al. (2007). Psychotropic medications and the risk of fracture: a meta-analysis. *Drug Saf.* 30(2), 171–84. doi: 10.2165/00002018-200730020-00006.

[483] Vuong C, et al. (2010). The effects of opioids and opioid analogs on animal and human endocrine systems. *Endocr. Rev*, 31(1), 98–132. doi: 10.1210/er.2009-0009

[484] Angst MS, Clark JD. 2006. Opioid-induced hyperalgesia: a qualitative systematic review. Anesthesiology, 104:570–87.

serious fecal impaction;[485] and chronic dry mouth, which can lead to tooth decay.[486] Providing prescribers with accurate information through a large-scale counter-detailing campaign and result in more informed risk/benefit appraisals. Indeed, one of the lessons learned from the nineteenth century opioid addiction epidemic was that physicians were educable.

In 2013, the New York City Department of Health and Mental Hygiene released emergency room guidelines on opioid prescribing.[487] Recommendations included in the guidelines call for substituting nonopioid analgesics when possible, avoiding use of extended-release opioid, and limiting the supply to three days. Reducing patient exposure to opioids and reducing the supply of excess opioids in the homes of discharged patients may be effective strategies for preventing opioid addiction that can occur from both medical and nonmedical opioid use. In 2013, New York City also launched an effective campaign on Staten Island, which utilized former pharmaceutical sales representatives, to detail healthcare providers with accurate information about opioid risks and benefits.[488]

Although prescription opioids have an abuse liability similar to that of heroin, they are commonly perceived as less risky.[489] Individuals who perceive opioid risks use to be low may be more likely to misuse them. Evidence suggests that people who perceive a low level of risk from opioids were 9.6 times more likely to use them nonmedically, as compared with those who perceive these medications as harmful.[490] Although the ability for causal inference from cross sectional surveys is limited, these finding suggest that social marketing campaigns designed to increase the public's perceived harmfulness of prescription opioids may be an effective prevention strategy.

[485] Tuteja AK, et al. (2010). Opioid-induced bowel disorders and narcotic bowel syndrome in patients with chronic non-cancer pain. *Neurogastroenterol. Motil,* 22(4), 424–30. doi: 10.1111/j.1365-2982.2009.01458.x.

[486] Thomson MW, et al. (2006). Xerostomia and medications among 32-year-olds. *Acta. Odontol. Scand,* 64(4), 249–54. doi: 10.1080/00016350600633243

[487] N.Y. City Dep. Health Ment. Hyg. 2013. New York City Emergency Department Discharge Opioid Prescribing Guidelines. Long Island City, NY: NYC Health *Available at* http://www.nyc.gov/html/doh/downloads/pdf/basas/opioid-prescribing-guidelines.pdf

[488] Kattan JA, Tuazon E, Paone D, et al. (2016). Public Health Detailing-A Successful Strategy to Promote Judicious Opioid Analgesic Prescribing. *Am J Public Health,* 106(8), 1430-1438. doi: 10.2105/AJPH.2016.303274

[489] Comer SD, et al. (2008). Abuse liability of prescription opioids compared to heroin in morphine-maintained heroin abusers. *Neuropsychopharmacology,* 33(5), 1179–91; Johnston LD, et al. (2014). Monitoring the future National Survey Results on Drug Use: 1975–2013. Overview, key findings on adolescent drug use. Ann Arbor, MI: Inst.Soc. Res., Univ. Mich.

[490] Arria AM, et al. (2008). Perceived harmfulness predicts nonmedical use of prescription drugs among college students: interactions with sensation-seeking. *Prev. Sci*., 9(3), 191–201. doi: 10.1007/s11121-008-0095-8

Secondary Prevention

The aim of secondary prevention is to screen for a health condition after its onset but before it causes serious complications. Efforts to identify and treat opioid-addicted individuals early in the course of the disease are likely to reduce the risk of overdose, psychosocial deterioration, transition to injection opioid use, and medical complications.

Physicians are frequently the source of opioids for opioid-addicted medical and nonmedical users.[491] Contacts with medical professionals present valuable opportunities for early identification of opioid addiction. However, detection of opioid addiction in opioid users can be very difficult. Opioid-addicted chronic pain patients may demonstrate aberrant drug-related behaviors, such as presenting for early refills. However, some opioid-addicted pain patients, especially those prescribed high doses, may not demonstrate drug-seeking behavior. Opioid-addicted individuals receiving opioid prescriptions are often reluctant to disclose their concerns about addiction with prescribers because they fear being judged, being cut off from a legitimate supply, or being labeled as malingerers for feigning pain.

The difficulty of diagnosing opioid addiction in individuals motivated to conceal their condition suggests that prescribers should seek collateral information before prescribing opioids. Urine toxicology can be used to verify a patient's self-reported drug ingestion history. However, urine toxicology of patients on long-term opioids is not a reliable strategy for identifying opioid addiction. Urine toxicology cannot determine if a patient is taking extra doses or if a patient is using opioids by an intranasal or injection route.

Opioid-addicted individuals may receive opioid prescriptions from multiple providers, a practice referred to as "doctor shopping." Doctor shoppers can be identified through use of state prescription drug monitoring programs (PDMPs). With adequate funding states could use PDMPs to identify individuals with likely opioid addiction and assign them care navigators to link them to treatment.

Tertiary Prevention

Tertiary prevention strategies involve both therapeutic and rehabilitative measures once a disease is firmly established. The goal of tertiary prevention of opioid addiction is to prevent overdose deaths, medical complications, psychosocial deterioration, transition to injection drug use, and injection-related infectious diseases. Doing so is accomplished mainly by ensuring that opioid addicted individuals can access effective and affordable opioid addiction treatment.

Treatment of opioid addiction includes pharmacotherapies and psychosocial approaches, including residential treatment, mutual-help programs (e.g., Narcotics Anonymous), and 12-Step treatment programs. These modalities may be used as stand-alone interventions or in combination with pharmacotherapy. Psychosocial opioid addiction treatment approaches show

[491] Jones CM, et al. (2014). Sources of prescription opioid pain relievers by frequency of past-year nonmedical use: United States, 2008–2011. *JAMA Intern. Med*., 174(5), 802–3. doi:10.1001/jamainternmed.2013.12809

value and are an important treatment option.[492] However, research with greater specificity and consistency is needed to better evaluate outcomes.

Pharmacotherapies for opioid addiction include agonist maintenance with methadone and partial-agonist maintenance with buprenorphine and antagonist treatment with naltrexone, which is available in a monthly injection. Methadone and buprenorphine work by controlling cravings. Naltrexone works by preventing opioid-addicted individuals from feeling the effects of opioids. Naltrexone may be helpful in highly motivated and carefully selected patients. However, patients treated with naltrexone may be at increased risk of overdose death should relapse occur.[493] Multiple well-designed randomized controlled trials provide strong evidence that buprenorphine maintenance and methadone maintenance are safe and effective treatments for opioid addiction.[494] Both buprenorphine and methadone treatment are associated with reduced overdose risk and improved maternal and fetal outcomes in pregnancy.[495] Despite strong evidence supporting the use of buprenorphine and methadone, access to treatment remains inadequate.

Methadone poses a substantially greater risk of respiratory depression than does buprenorphine and can be obtained only from licensed opioid treatment programs (OTPs). The lack of OTPs in many communities presents a major challenge to expanding access to methadone. In contrast, buprenorphine, a partial opioid agonist, has a better safety profile than does methadone and can be prescribed in an office-based setting. Barriers to accessing buprenorphine include federal limits on the number of patients a physician may treat, ineligibility of nurse practitioners to prescribe it, and inadequate integration of buprenorphine into primary care treatment. Access to buprenorphine treatment could be expanded if the federal government eased or remove regulatory barriers.

[492] Reif S, , et al. (2014). Residential treatment for individuals with substance use disorders: assessing the evidence. *Psychiatr. Serv*. 65(3), 301–12. doi:10.1176/appi.ps.201300242

[493] Digiusto E, et al. (2004). Serious adverse events in the Australian National Evaluation of Pharmacotherapies for Opioid Dependence. *Addiction*, 99(4), 450–60. doi: 10.1111/j.1360-0443.2004.00654.x

[494] Sees KL, et al. (2000). Methadone maintenance for opioid dependence. *JAMA* 284(6), 694–95.; Strain EC, et al. (1999). Moderate versus high-dose methadone in the treatment of opioid dependence: a randomized trial. *JAMA*, 281(11), 1000–5. doi: 10.1001/jama.281.11.1000; Fudala PJ, et al. (2003). Office-based treatment of opiate addiction with a sublingual-tablet formulation of buprenorphine and naloxone. *N. Engl. J. Med*., 349(10), 949–58. doi: 10.1056/NEJMoa022164; Johnson RE, et al. (2000). A comparison of levomethadyl acetate, buprenorphine, and methadone for opioid dependence. *N. Engl. J.Med*. 343(18), 1290–97. doi: 10.1056/NEJM200011023431802

[495] Coyle MG, et al. (2012). Neonatal neurobehavior effects following buprenorphine versus methadone exposure. *Addiction,* 107(1), 63–73. doi: 10.1111/j.1360-0443.2012.04040.x; Jones HE, et al. (2010). Neonatal abstinence syndrome after methadone or buprenorphine exposure. *N. Engl. J. Med*. 363, 2320–31. DOI: 10.1056/NEJMoa1005359; McCarthy JJ, Leamon MH, Parr MS, Anania B. (2005). High-dose methadone maintenance in pregnancy: maternal and neonatal outcomes. *Am. J. Obstet. Gynecol*., 193, 606–10. doi: 10.1016/j.ajog.2005.03.072

Harm-reduction approaches. Tertiary prevention strategies also include harm-reduction approaches to improving health outcomes and reducing overdose deaths. In the subset of opioid addicted individuals who are heroin injection drug users, evidence suggests that access to syringe exchange programs can prevent HIV infection.[496] These efforts have been less effective at preventing hepatitis C infection, which, because of the opioid crisis, is increasing rapidly in young, white IDUs.[497]

Expanding access to naloxone, an opioid overdose antidote, can prevent overdose deaths by reversing life-threatening respiratory depression. In the 1990s, syringe exchange programs began distributing naloxone to injection drug users for the purpose of rescuing peers. Evidence shows that clients of syringe exchange programs demonstrated the ability to successfully reverse overdoses when they had been provided with naloxone and training.[498] In addition, providing family members of opioid-addicted individuals and non-paramedic first responders with naloxone may be an effective strategy for rescuing overdose victims.[499]

[496] Des Jarlais DC, et al. (2005). HIV incidence among injection drug users in New York City, 1990 to 2002: use of serologic test algorithm to assess expansion of HIV prevention services. *Am. J. Public Health,* 95(8), 1439–44. doi: 10.2105/AJPH.2003.036517

[497] Hagan H., et al. (2010). Attribution of hepatitis C virus seroconversion risk in young injection drug users in 5 US cities. *J. Infect. Dis,* 201(3), 378–85. doi:10.1086/649783

[498] Seal KH, et al. (2005). Naloxone distribution and cardiopulmonary resuscitation training for injection drug users to prevent heroin overdose death: a pilot intervention study. *J. Urban Health,* 82(2), 303–11. doi: 10.1093/jurban/jti053

[499] Davis CS, et al. (2014). Expanded access to naloxone among firefighters, police officers, and emergency medical technicians in Massachusetts. *Am. J. Public Health*, 104(8), e7–9. doi: 10.2105/AJPH.2014.302062; Williams AV, Marsden J, Strang J. (2014). Training family members to manage heroin overdose and administer naloxone: randomized trial of effects on knowledge and attitudes. *Addiction*, 109(2), 250–59. doi: 10.1111/add.12360

Pursuant to 28 U.S.C. S 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed on August 3, 2020.

Andrew Kolodny, M.D.